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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 2006 and Fiscal Year 2007

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APPENDICES

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

Historical Context

The establishment and implementation of policies for the inclusion of women and minorities in clinical research funded by the National Institutes of Health (NIH) has its origins in the women's health movement. Following the issuance of the report of the Public Health Service Task Force on Women's Health in 1985, the NIH established a policy in 1986 for the inclusion of women in clinical research. This policy, which ***urged*** the inclusion of women, was first published in the NIH Guide to Grants and Contracts in 1987. Later that year, minority and other scientists at the NIH recognized the need to address the inclusion of minority populations. Therefore, in a later 1987 version of the NIH guide, a policy ***encouraging*** the inclusion of minorities in clinical studies was first published.

In order to ensure that the policies for inclusion were firmly implemented by NIH, the Congress made what had previously been policy into Public Law, through a section in the NIH Revitalization Act of 1993 (PL 103-43)[1], entitled *Women and Minorities as Subjects in Clinical Research*. In 1994, the NIH revised its inclusion policy to meet this mandate that women and minorities must be included in all of its clinical research studies. The Revitalization Act essentially reinforced the existing NIH policies, but with four major differences:

- that NIH ensure that women and minorities and their subpopulations be included in all clinical research;
- that women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to allow for valid analyses of differences in intervention effect;
- that cost is not allowed as an acceptable reason for excluding these groups; and,
- that NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies

Revised inclusion guidelines developed in response to this law were published in the *Federal Register*[2] in March 1994, and they became effective in September 1994. The result was that NIH could not and would not fund any grant, cooperative agreement or contract or support any intramural project to be conducted or funded in Fiscal Year 1995 and thereafter which did not comply with this policy.

Strategies to ensure uniform implementation of the revised guidelines across the NIH were developed through the establishment and deliberations of an NIH Tracking and Inclusion Committee made up of representatives of the directors of each of the Institutes and Centers (ICs). This trans-NIH committee, convened by the Office of Research on Women's Health (ORWH) and co-chaired with a senior IC official, meets on a regular basis, focusing on consistent and widespread adherence to the NIH guidelines by all the ICs. Working in collaboration with the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and other components of the NIH, the ORWH coordinates the activity of developing and establishing data collection and reporting methodologies to ensure uniform standards and definitions in the reporting of data on women and minority participants in NIH-funded clinical research.

To ensure NIH-wide adherence to the revised inclusion guidelines, in 1994 NIH conducted extensive training on the revised inclusion guidelines. In June 1994, the ORWH convened a meeting of Institutional Review Board (IRB) chairs to discuss their role in implementing the revised policy. Training was especially important in light of 1990 General Accounting Office (GAO) findings that an earlier policy was inconsistently applied and had not been well communicated or understood within the NIH or in the research community. A variety of outreach activities were initiated to explain the revised policy to the scientific research community and to clear up common misunderstandings about the new requirements.

GAO Report, May 2000: Recommendations and Actions Taken

Following a Congressional request for an assessment of NIH's progress in implementing the1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled *Women's Health - NIH Has Increased Its Efforts to Include Women in Research.*[3] It concluded that in the past decade, NIH has made significant progress in implementing a strengthened policy on including women in clinical research.

The GAO report also included two specific recommendations to the Director of NIH to ensure the following:

- that the requirement be implemented that Phase III clinical trials be designed and carried out to allow for the valid analysis of differences between women and men and communicate this requirement to applicants as well as requiring peer review groups to determine whether each proposed Phase III clinical trial is required to have such a study design, and that summary statements document the decision of the initial reviewers; and

- that the NIH staff who transmit data to the inclusion tracking data system receive ongoing training on the requirements and purpose of the system.

Immediately following the release of this report, a *NIH Subcommittee Reviewing Inclusion Issues* was formed, consisting of representatives from several ICs, ORWH, OER, and OIR, to reexamine NIH's system for tracking data on the inclusion of women and minorities in clinical research, recommend any necessary changes to improve its accuracy and performance, and reiterate the NIH policy. Several actions resulted to clarify the requirement for NIH-defined Phase III clinical trials to include women and minority groups, if scientifically appropriate, and for analysis of sex/gender and/or racial/ethnic differences to be planned and conducted by investigators engaged in NIH-funded research. Significant actions in 2001 included:

- **Updating the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research** and posting it on the ORWH home page http://orwh.od.nih.gov/inclusion.html and NIH web page, *Inclusion of Women and Minorities Policy Implementation* at: http://grants.nih.gov/grants/funding/women_min/women_min.htm.

- **Developing a new term and condition of award** statement for awards made after October 1, 2000 that have NIH-defined Phase III clinical trials.

- **Incorporating language in the NIH solicitations for grant applications and contract proposals to clarify the submission requirement for NIH-defined Phase III clinical trials**, a description of plans for sex/gender and/or race/ethnicity analysis including subgroups, if applicable, and reporting accrual annually and results of analyses, as appropriate.

- **Guidelines and instructions for reviewers and Scientific Review Officers (SROs) were developed** to emphasize and clarify the need to review research proposals that are classified as NIH-defined Phase III clinical trials for both inclusion requirements and issues related to analyses by sex/gender and/or race/ethnicity. Instructions were developed for the proper documentation to include in summary statements to address adherence to these policies.

Training to ensure compliance with this policy was provided to NIH program and review officials, grants and contracts management staff, and current and prospective research investigators. Several initiatives were implemented for review, grants management and program staff since 2000, including specific topics addressing revisions to the NIH Inclusion policy, a grants policy update and Scientific Review Officer (SRO) orientation on specific issues related to review meetings and proceedings.

Format Changes for Reporting Race and Ethnicity Data as of FY2002

Beginning in FY2002, NIH changed how data are reported based on the 1997 Office of Management and Budget (OMB) Directive 15 minimum standards for maintaining, collecting and reporting data on race and ethnicity. Implementation of the 1997 OMB standards involved a number of changes including collecting and reporting information on race and ethnicity separately, whereas the 1977 OMB standards used a combined race and ethnicity format. NIH aggregate population data tables describe data using both the 1997 and 1977 OMB standards for reporting data on race and ethnicity. Since 2002, the number of studies reporting data using the 1997 format (NEW FORM) has steadily increased, while the number of studies using the 1977 format (OLD FORM) has steadily decreased as the studies funded prior to FY2002 are completed.

The 1997 OMB reporting format (NEW FORM) and standards does not allow direct comparison of ethnic and racial data with similar data collected under the 1977 OMB reporting format (OLD FORM) and standards because the categories and methods for collecting the data are fundamentally different. Changes in the standardization of definitions and business rules across the NIH for improving the data entered in the population tracking system are reflected in data reported beginning in FY2002. While implementation of these changes will improve the consistency and comparability for future reporting, comparisons with prior FY 2002 data are difficult.

As demonstrated below, the primary differences are: (1) the Hispanic population is considered an ethnic category and reported separately from racial data; (2) there is a separate racial category for Asian population data and Hawaiian and Pacific Islander population data; and 3) respondents are given the option of selecting more than one race. (See Appendix H)

Race and ethnicity data from the OLD and NEW Forms are combined differently as described below for purposes of reporting on the minority population enrolled in NIH clinical research:

- the OLD FORM uses the 1977 OMB combined Race and Ethnicity Format, which has mutually exclusive categories, and allows Hispanics to be reported as either "Hispanic, Not White" or "White".

- the NEW FORM uses the 1997 OMB Race and Ethnicity Categories, with separate reporting for Ethnicity (Hispanic or Latino; Not Hispanic or Latino) and Race (Part A); in this format, an individual is classified both by Ethnic Category and by Race Category. Part B of the NEW FORM therefore provides a distribution of only "Hispanics or Latinos" by the five main Race categories. Since minority categories are defined to include both "Hispanic or Latino ethnicity" and non-white racial categories when providing summary totals of minorities, it is necessary to add White Hispanics" and "Unknown/Other Hispanics" based on their ethnicity to the non-white racial categories.

- Hispanics are defined by country of origin, and may be identified as belonging to any one, or more than one, race category.

OLD FORM (1977) versus NEW FORM (1997)		
Race/Ethnicity Category	**Minority Total Old Form**	**Minority Total New Form**
OLD FORM: Combined 1977 OMB Race/Ethnicity Categories		
American Indian/Alaska Native	**X**	
Asian/Pacific Islander	**X**	
Black or African American	**X**	
Hispanic, Not White	**X**	
White		
Unknown/Other		

NEW FORM: Separate 1997 OMB Race/Ethnicity Categories		
Part A: Total Enrollment Report		
Ethnic Category		
Hispanic or Latino**		
Not Hispanic or Latino		
Unknown (ethnicity not reported)		
Ethnic Category Total of All Subjects*		
Racial Categories		
American Indian/Alaska Native		**X**
Asian		**X**
Black or African American		**X**
Hawaiian/Pacific Islander		**X**
White		
More Than One Race		**X**
Unknown/Other		
Racial Categories: Total of all Subjects*		
Part B: Hispanic Enrollment by RACE		
American Indian/Alaska Native		
Asian		
Black or African American		
Hawaiian/Pacific Islander		
White (Hispanic)		**X**
More Than One Race		
Unknown/Other (Hispanic)		**X**
Racial Categories: Total of Hispanics or Latinos**		

***** The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects"

****** The "Hispanic or Latino"(Part A) must be equal to "Racial Categories: Total of Hispanics or Latinos"(Part B).

Continuing Implementation and Monitoring Activities

In FY2007, two training sessions were developed and sponsored by the Office of Extramural Research. The half-day training sessions were held in April and September in the Natcher Conference Center, Bethesda, MD and webcast throughout the NIH community. While some staff participated in the training via the web, approximately 300 grants management, program and review staff physically attended each session. Participants received a certificate of completion and if appropriate extramural scientist administrator (ESA) credits after completing a short test. The Office of Extramural Research (OER) has made available training materials on the Population tracking system website through the NIH Intranet. The training subcommittee of the full NIH Tracking and Inclusion committee has developed new training documents and methods of training for NIH staff and the extramural research community. Further information regarding training initiatives since the 2000 GAO report is discussed in the background section of the Appendices (See Appendix A).

The PHS 398 Grant Application was significantly revised to provide additional instructions about the Women and Minorities Inclusion Policy and the revised form became mandatory as of May 10, 2005. These PHS 398 instructions about the Women and Minorities Inclusion Policy have also been included in the new federal application form SF-424 (R&R) for NIH grants using the federal Grants.gov system (see http://era.nih.gov/ElectronicReceipt/). The application instructions included two significant changes in definitions. First, the NIH required use of a revised definition of clinical research that was reported in the 1997 Report of the NIH Director's Panel on Clinical research and adopted by NIH. Secondly, the Office of Management and Budget (OMB) Directive 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting", revised the definitions for the racial and ethnic categories to be used when reporting population data (see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html). In addition, NIH policy reemphasized that that NIH-defined Phase III clinical trials must be designed and conducted in a manner to allow for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other subjects.

Communication and Outreach Efforts to the Scientific Community

NIH staff provides outreach to the scientific community to help increase understanding of the revised inclusion policy and OMB requirements. These training and outreach efforts are designed to improve understanding of the sex/gender and minority inclusion policy and assist investigators and NIH staff to appropriately address these issues throughout the research grant and contract process. Investigators are instructed to address women and minority inclusion issues in the development of their applications and proposals for clinical research.

Reference documents such as the *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research* (http://orwh.od.nih.gov/inclusion/outreach.pdf) and the *Frequently Asked Questions (FAQs) for the Inclusion , Recruitment and Retention of Women and Minority Subjects in Clinical Research* (http://orwh.od.nih.gov/inclusion/outreachFAQ.pdf) have been published and distributed for investigators and NIH staff. These publications discuss the elements of recruitment and retention, the NIH inclusion policy, 1997 OMB requirements for reporting race and ethnicity data, as well as information for application submission, peer review, and funding. Both are posted on the ORWH website http://orwh.od.nih.gov as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm. The revised Outreach Notebook and FAQs continue to be available to the research community to further explore the inclusion policy and its intent. Additionally, a slide show available electronically and in hard copy, "Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know!" was developed for NIH staff to assist them in working with the extramural community.

Monitoring Compliance: Extramural and Intramural Population Data Analysis

As a way of monitoring compliance with the policy, we have provided the aggregate data tables compiled from each NIH Institute and Center. Analysis of aggregate NIH data on inclusion for FY2006 and FY2007 document that substantial numbers of women and men, especially non-minority men, and minorities have been included as research subjects in NIH-defined Phase III clinical trials and other human subject research studies during these fiscal years. Because the data included in the tables are aggregate data from across NIH, it does provide documentation of the tracking and inclusion across the NIH, and some degree of analysis of the data. But caution should be utilized in not over-interpreting the figures that are provided. The NIH Tracking and Inclusion committee has provided for the reader's interest, conclusions that can be reasonably drawn from the data.

When assessing inclusion data, enrollment figures should not be directly compared to the national census figures. The goal of the NIH policy is not to satisfy any quotas for proportional representation, but rather to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will be generalizable to the entire population of the United States. The numbers of women or minority subgroups included in a particular study depends upon the scientific question addressed in the study and the prevalence among women and minority subpopulations of the disease, disorder, or condition under investigation.

Scientific Review Groups are instructed to focus on scientific considerations when assessing the planned enrollment for a particular study. The Scientific Review Group (SRG) determines if the implementation plan for an application is unacceptable if it: 1) fails to provide sufficient information about target enrollment; 2) does not adequately justify limited or lack of inclusion of women or minorities; or 3) does not realistically address recruitment and retention. For NIH-defined Phase III clinical trials, the Scientific Review Group (SRG) also evaluates the description of plans to conduct analyses, as appropriate, to address differences in the intervention effect by sex/gender and/or racial/ethnic groups. Applications with unacceptable inclusion plans cannot be funded until NIH staff is assured that revised inclusion plans from the investigators meet the inclusion policy requirements. Research awards covered by this policy require the grantee to report annually on enrollment of women and men, and on the race and ethnicity of research participants so that accrual can be monitored.

NIH has monitored aggregate demographic data for study populations through the evolving NIH computerized tracking system since fiscal year 1994, and tracking the inclusion of women and minorities in clinical studies is well established in all ICs. Members of the NIH Tracking and Inclusion Committee continuously work on ways to refine and improve data collection methods and the quality of the data entered by each IC into this system. In May 2002, the NIH successfully deployed a new population tracking system for monitoring the inclusion of women and minorities in clinical research. This system provides easier data entry and project monitoring of investigator data reporting for NIH staff. An *eRA Population Tracking User Group* consisting of representatives from several ICs provides continuous feedback related to system use.

The aggregate data enable the NIH to monitor inclusion in order to formulate more specific questions about gaps in enrollment and to design studies to respond to those questions. Data compiled allows for longitudinal examination of trends and continued monitoring of compliance, although this will be more difficult for minority trends because of a change in how these data are collected (see next section).

A review of intramural inclusion data indicates that the intramural research program continues to be compliant with the reporting requirements adhered to by the extramural community and outlined in the NIH Implementation Guidelines on the Inclusion of Women and Minority Subjects in Research Studies.

The Clinical Center Medical Executive Committee (MEC) has taken a leading role in assuring that investigators conducting clinical research protocols in the Clinical Center are trained and competent in the conduct of clinical research. The MEC designed and endorsed the Standards for Clinical Research within the NIH Intramural Research Program which set forth guidelines for the infrastructure, training, education, and monitoring required for safe and effective conduct of clinical research.

DEFINITIONS:

Clinical Research as defined by the 1997 Report of the NIH Director's Panel on Clinical Research, http://www.nih.gov/news/crp/97report/execsum.htm

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies;
(2) Epidemiologic and behavioral studies; and
(3) Outcomes research and health services research

NIH-Defined Phase III Clinical Study

For the purpose of these guidelines, an NIH-defined "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Valid Analysis

The term "valid analysis" means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- allocation of study participants of both sexes/genders (males and females) and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- unbiased evaluation of the outcome(s) of study participants, and
- use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Significant Difference

For purposes of this policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

Domestic organization

A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities

Foreign institution
An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PI.

CONCLUSION AND CURRENT STATUS

NIH staff continues to monitor, document, and work with grantees and contractors to ensure compliance with the inclusion policy. Program Officials provide technical assistance to investigators as they develop their applications and proposals throughout the application process. Review Officials introduce and discuss with reviewers the Guidelines/Instructions for reviewing the Inclusion of Women and Minorities in Clinical Research as well as the instructions and requirements for designing Phase III Clinical Trials in order that valid analyses can be conducted for sex/gender and ethnic/racial differences. At the time of award and submission of progress reports, program officials monitor and verify that inclusion policy requirements are met. When new and competing continuation applications that are selected for payment are deficient in meeting policy requirements, grants management staff and program officials are required to withhold funding until the principal investigator has satisfactorily addressed the policy requirements.

References

1. Public Law 103-43. National Institutes of Health Revitalization Act of 1993. 42 USC 289 (a)(1).

2. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508-14513 (1994).

3. *Women's Health: NIH Has Increased Its Efforts to Include Women in Research* (GAO/HEHS-00-96, May, 2000).

4. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, NIH Guide for Grants and Contracts, Amended 2001.

For Additional Information on the implementation of the inclusion policy, please visit:

NIH Office of Extramural Research Inclusion of Women and Minorities Policy Implementation Website:
http://grants.nih.gov/grants/funding/women_min/women_min.htm

Revitalization Act of 1993, 42 USC 289 (a)(1): http://grants.nih.gov/grants/guide/notice-files/not94-100.html

NIH Policy on Reporting Racial and Ethnicity Data: Subjects in Clinical Research, NIH Guide for Grants and Contracts Web page: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html

Office of Research on Women's Health Website: http://orwh.od.nih.gov/inclusion.html

Aggregate Enrollment Data Tables For Extramural and Intramural Research Protocols

Fiscal Year 2007 Summary Reports
Thirteen -year Trend Summary Reports

Summary Report of NIH Inclusion Data

NIH AGGREGATE POPULATION DATA REPORTED IN FY2006 and FY2007

The following section is provided in order to guide consideration of the data especially in trend of human subjects participation in NIH-funded extramural and intramural clinical research. Because new studies are added each year and other studies are ending, it is not appropriate to compare data over time or to compare data with census population data. Looking at the trend data represents the best interpretation of the aggregate data. Data on inclusion is tabulated from human subject populations in NIH-defined Phase III clinical trials and other human subject research studies. NIH clinical research studies are determined in accordance with the NIH definition of clinical research to include, for example, non-intervention clinical research, clinical trials, epidemiologic studies, behavioral studies, and database studies.

Analysis of aggregate NIH data on inclusion for FY2006 and FY2007 document that substantial numbers of women and men, especially non-minority men, and minorities have been included as research subjects in NIH-defined Phase III clinical trials and other human subject research studies during these fiscal years. Because the data included in the tables are aggregate data from across NIH, it does provide documentation of the tracking and inclusion across the NIH, and some degree of analysis of the data. But caution should be utilized in not over-interpreting the figures that are provided. The NIH Tracking and Inclusion committee has 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. The FY2006 and FY2007 data tables may vary slightly or differ from prior reported summary data in an effort to better clarify reporting.

NIH CLINICAL RESEARCH: Fiscal Years 2006 and 2007

In FY2006 there were 15,320 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,758 protocols reported human subject participation as noted in this report’s trend summary tables. Of these, 95.7% were domestic protocols and 4.3% were foreign protocols. Approximately 14.8 million participants were enrolled in extramural and intramural research protocols of which 77.0% were domestic participants and 23.0% were foreign participants. Of the 14.8 million participants, 63.9% were women, 34.9% were men and 1.3% did not provide sex identification. Further, 43.1% of the total participants, and 28.9% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (*Table 6*)

Correspondingly, 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. Of these, 95.9% were domestic protocols and 4.1% were foreign protocols. Approximately 17.4 million participants were enrolled in extramural and intramural research protocols of which 92.6% were domestic participants and 7.4% 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. Further, 29.9% of the total participants, and 26.5% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (*Table 1*)

While the number of participants in all extramural and intramural clinical research increased (14.8M in FY2006 and 17.4M in FY2007), there was no significant change in the ratio of women and men (63.9%F and 34.9%M in FY2006; and 58.2%F and 39.5%M in FY2007).

NIH Defined Phase III Clinical Research: FY2006 and FY2007

In FY2006 there were 760 extramural and intramural Phase III clinical research protocols, of which 624 protocols reported human subject participation as noted in this report's trend summary tables. Of these, 90.4% were domestic protocols and 9.6% were foreign protocols. Approximately 499,430 participants were enrolled in extramural and intramural Phase III research protocols of which 80.2% were domestic participants and 19.8% were foreign participants. Of the 499,430 participants, 62.9% were women, 36.0% were men and 1.1% did not provide sex identification. Further, 33.5% of the total participants, and 20.7% of Domestic-only participants, in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (*Table 3*)

According to the trend summaries in this report, of the 215 extramural and intramural Phase III research protocols that report following the 1977 OMB standards in FY2006, minority representation was highest for Blacks (not Hispanic) at 8.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 4.1%, Asian/Pacific Islanders were 7.3% and Whites (not Hispanic) 76.5% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*Table 7*)

Moreover, in FY 2006, there were 409 extramural and intramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 18.8% and lowest for Hawaiian/Pacific Islanders 0.2%. Asians represented 12.0%, American Indian/Alaska Natives 1.7% and Whites 47.0% of participants. Participants identifying as *More Than One* Race were 1.6% of the total number of participants. In addition, 18.7% did not identify a race category. Of the 409 extramural and intramural Phase III research protocols designating an ethnicity in FY2006, 75.0 % of total participants identified as "Not Hispanic", 11.5 % of the total participants identified as "Hispanic or Latino", and 13.5% of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (*Table 7*)

Correspondingly, in FY2007 there were 766 extramural and intramural Phase III clinical research protocols, of which 621 protocols reported human subject participation as noted in this report's trend summary tables. Of these, 92.9% were domestic protocols and 7.1% were foreign protocols. Approximately 591,159 participants were enrolled in extramural and intramural Phase III research protocols of which 70.3% were domestic participants and 29.7% were foreign participants. Of the 591,159 participants, 54.9% were women, 42.2% were men and 2.8% did not provide sex identification. Further, 41.4% of the total participants, and 20.6% of Domestic-only participants, in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (*Table 3*)

According to the trend summaries in this report, of the 197 extramural and intramural Phase III research protocols that report following the 1977 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% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*Table 7*)

Moreover, in FY 2007, there were 424 extramural and intramural Phase III research protocols reporting data following the current 1997 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. 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 7*)

While the number of participants in Phase III extramural and intramural clinical research slightly increased (499,430 in FY2006 and 591,159 in FY2007), there was an increase in the ratio of women and men (62.9%F and 36.0%M in FY2006 and 54.9%F and 42.2% in FY2007).

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

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2006 and 2007

In FY2006, there were 13,522 extramural clinical research protocols, including Phase III and other clinical studies, of which 9,235 protocols reported human subject participation. Of these, 95.7% were domestic protocols and 4.3% were foreign protocols. Approximately 13.02 million participants were enrolled in extramural research protocols of which 76.6% of the total enrollment is domestic participants and 23.4% of the total enrollment is foreign participants. Of the 13.02 million participants, 65% were women, 33.8% were men and 1.2% did not provide sex identification. Further, 45.9% of the total participants were reported as minorities following the OMB categories for race and ethnicity. *(See 2006 Report, Table 2 and Appendix table 3*A)

Correspondingly, 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, 95.9% were domestic protocols and 4.2% were foreign protocols. 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% (from 23.4%) of the total enrollment is foreign participants. Of the 13.9 million participants, 61.8% were women, 35.5% were men and 2.62% did not provide sex identification. Further, 31.4% of the total participants were reported as minorities following the OMB categories for race and ethnicity. *(Table 2 and Appendix Table 3*A)

While the number of participants in all extramural clinical research increased (13.02 million in FY2006 and 13.9 million in FY2007), there was no significant change in the ratio of women and men (65%F and 34%M in FY206 and 61.8%F and 35.5%M).). However, when sex-specific studies were excluded, the proportions of women and men in all extramural clinical research were proportional to the percentages of the general population. (46.5% F and 49.8 % M).

NIH Defined Phase III Extramural Clinical Research: FY2006 and FY2007

In FY2006 there were 707 extramural Phase III clinical research protocols, of which 580 protocols reported human subject participation as noted in this report’s trend summary tables. Approximately 467,954 participants were enrolled in extramural Phase III research protocols of which 63.5% were women, 35.4% were men and 1% did not provide sex identification. *(See 2007 Report*)

In FY2007 there were 710 extramural Phase III clinical research protocols, of which 616 protocols reported human subject participation as noted in this report’s trend summary tables. Approximately 547,687 participants were enrolled in extramural Phase III research protocols of which 61.8% were women, 35.5% were men and 2..62% did not provide sex identification. *(Table 4 and Appendix Table* 5A)

According to trend summaries in the 2007 report, in FY2006, there were 382 extramural Phase III research protocols reporting data following the current 1977 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 19.7% and lowest for Hawaiian/Pacific Islanders 0.2%. Asians represented 12.67%, American Indian/Alaska Natives 1.8% and Whites 46.32% of participants. Participants identifying as *More Than One* Race were 15% of the total number of participants. In addition, 17.8 % did not identify a race category. Of the 382 extramural Phase III research protocols designating an ethnicity in FY 2006, 75.8 % of total participants identified as "Not Hispanic", 11.14 % of the total participants identified as "Hispanic or Latino", and 13.1 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately.

Correspondingly in FY2007, there were 399 extramural Phase III research protocols reporting data following the 1997 OMB standards for reporting race and ethnicity. Minority representation by race was highest for Blacks at 23.2% and lowest for Hawaiian/Pacific Islanders 0.13%. Asians represented 13.1%, American Indian/Alaska Natives 2.59% and Whites 34.3% 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, 67.7 % of total participants identified as "Not Hispanic", 17.7% of the total participants identified as "Hispanic or Latino", and 14.4 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (*See 2007 Report, Table 4 and Appendix Table 5A*)

While the number of participants in extramural Phase III extramural clinical research protocols slightly increased (707 in FY2006 and 710 in FY2007), there was an increase in the ratio of women and men (63.9%F and 3.4%M in FY2006 and 55.1 %F and 41.8% M in FY2007).

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2006 and 2007

Substantial numbers of women and minorities were included in NIH intramural studies in FY 2006 and FY2007.

In FY2006 there were 1,798 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,523 protocols reported human subject participation. Approximately 1.8 million participants were enrolled in intramural research protocols of which 55.4% were women, 43.0% were men and 1.6% did not provide sex identification. (*See Table 2 and Appendix Table 7A*)

In FY 2006, approximately 1.8 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 590 intramural research protocols that report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 19.9% and lowest for American Indian/Alaska Natives at 3.3%. Blacks (not-Hispanic) represented 7.2%, Hispanics 3.5%; and Whites (not Hispanic) 62.0% of the intramural research study population. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*See Appendix Table 7A*)

For 933 intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2006, the largest racial minority group was Asian at 8.6 % and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.07%. Blacks represented 5.0%, American Indian/Alaska Natives 0.4% and Whites 79.1% of participants in all intramural clinical research. Approximately 0.8% of participants reported *More Than One Race* as their racial category. In addition, 6.0 % did not identify a race category. Of the 933 intramural research protocols following the current 1997 OMB standards

designating an ethnicity in FY2006, 91.3 % of total participants identified as “Not Hispanic”, 4.1 % of the total participants identified as “Hispanic or Latino”, and 4.6 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (*See Appendix Table 7A*)
(*See 2006 Report, Table 2 and Appendix Table 7A*)

Correspondingly, 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. Approximately 3.5 million participants were enrolled in intramural research protocols of which 43.4% were women, 55.4% were men and 1.2% did not provide sex identification. (*See Table 2 and Appendix Table 7A*)

In FY 2007, 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 1977 OMB standards, minority representation was highest for Blacks (not-Hispanic) at 17.59% and lowest for American Indian/Alaska Natives at 0.17%. Asian/Pacific Islanders represented 3.65%, Hispanics 4.3%; 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 1977 OMB standards. (*See Appendix Table 7A*)

For 1,103 intramural clinical research studies that reported data following the current 1997 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 69.8% 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 1997 OMB standards designating an ethnicity in FY2007, 85.5 % of total participants identified as “Not Hispanic”, 4.19 % of the total participants identified as “Hispanic or Latino”, and 10.3 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (*See Appendix Table 7A*)

There was a decrease in female participants from 55.0% to 43% and a corresponding increase in male participants from 43% to 55%. The number of participants in all intramural clinical research significantly increased from 1.8M to 3.4M from FY2006 to FY2007.

NIH Defined Phase III Intramural Clinical Research: FY2006 and FY2007

In FY2006 there were 53 intramural Phase III clinical research protocols, of which 44 protocols reported human subject participation. Of these, 6.3% of the total number of protocols is domestic and 0.7% of the total number of protocols is foreign. Approximately 31,476 participants were enrolled in intramural Phase III research protocols of which 2.34% of the total enrollment is domestic participants and 3.5% are foreign participants. Of the 31,476 participants, 54% were women, 46% were men and 0% did not provide sex identification. Further, 54% of total participants in Phase III clinical research protocols were reported as minorities following the OMB categories for race and ethnicity.
(*See 2007 Report, Table 4 and Appendix Table 9A*)

Correspondingly, in FY2007 there were 38 intramural Phase III clinical research protocols, of which 36 protocols reported human subject participation. Of these, 4.5% of the total number of protocols is domestic and 0.5% of the total number of protocols is foreign. Approximately 43,472 participants were enrolled in intramural Phase III research protocols of which 5.67% of the total enrollment is domestic participants and 1.7% are foreign participants. Of the 43,472 participants, 52.8% were women, 47.2% were men and 0% did not provide sex identification. Further, 27.3% of total participants in Phase III clinical research protocols were reported as minorities following the OMB categories for race and ethnicity. (*Table 4 and* Appendix *Table 9A*)

There was a small decrease in women (54.7% to 52.8%) and corresponding increase in men (46.0% to 47%). The number of participants in Phase III intramural clinical research increased from 31,476 to 43,472 in FY2006 and FY2007.

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY1995 – FY2007

The following section provides trend data on the collection and reporting of human subject participation in NIH funded clinical research, including Phase III clinical studies. The data are also provided in terms of foreign and domestic participation and minority representation. 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 5 is a thirteen 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 10,914 in FY2007 – a 3.4 fold increase. Reported enrollment increased from approximately 1.0 million (FY1995) to 17.1 million (FY2007) – a 17.1 fold increase; minority enrollment increased from approximately 0.4 million (FY2002) to 5.2 million (FY2007) – a 13.9 increase in minority representation in NIH clinical research. Over the last six years, the total number of protocols reported with enrollment data has leveled off at about 10,000 protocols per year.

With the deployment of an updated population tracking system in 2002 and the OMB requirement to report data using a new 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 16.2 million (FY2007) – a 1.6 fold increase. Foreign enrollment increased from 0.9 million (FY2002) to 1.2 million (FY2007) – a 1.3 fold increase. Overall, the total enrollment has increased with domestic participation averaging between 75.9-92.7% and foreign participation averaging between 8.5-24.1%. In FY2007, domestic and foreign enrollment was 92.7% and 7.3% respectively.

Table 6 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 averaged between 51.7% and 63.9%, male participation in all extramural and intramural research averaged between 34.0% and 45%. Overall minority participation in all extramural and intramural clinical research averaged between 30% and 43%. Table 6E provides a comparison of domestic and foreign participation between FY2002 and FY2007. 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 6F shows domestic and foreign enrollment for the six-year period. Domestic minority enrollment varied between 24% and 29.1% of total domestic participation, while foreign minority enrollment varied between 73.6% and 90.9% of total foreign participation.

Table 7 is a summary report of NIH-funded Phase III extramural and intramural clinical research by sex/gender and minority representation following the old and new data reporting formats for domestic and foreign studies. The report demonstrates that female participation in NIH funded Phase III extramural and intramural clinical research generally averaged between 54.1% and 74.8% and male participation in NIH-funded Phase III extramural and intramural clinical research averaged between 24.3% and 44.6%. Overall minority participation in NIH-funded Phase III extramural and intramural clinical research increased from 22.5% to 41.4%. Table 7E provides a comparison of domestic and foreign participation between FY2002 and FY2007. 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%-24.5% of the total clinical research protocols with enrollment in the last six years. Table 7F shows domestic and foreign enrollment for the six-year period. Domestic minority enrollment varied between 20.7% 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 six year period shows that the small percentage of foreign protocols (6.7%) in FY2007 account for a significant proportion (27.5%) of the total foreign enrollment.

Tables 8-11 provide summary reports of 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 averaged between 58% and 67.3% while male participation averaged between 31.2 and 39.5%. (*Table 8)* For NIH-funded Phase III extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation averaged between 54.8 and 64.8% while male participation averaged between 34.4 and 44.8%. *(Table 9)* 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 10)* 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 11)*

Table 1. Summary of NIH Clinical Research Reported In FY2007: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

1A. PROTOCOLS REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Protocols with Enrollment	10,914	10,463	95.9%	451	4.1%
%	70.1%	70.5%		62.6%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,653	4,383	94.2%	270	5.8%
	29.9%	29.5%		37.4%	
Total Number of Protocols	**15,567**	**14,846**	95.4%	**721**	4.6%
%	100.0%	100.0%		100.0%	

See Table 1A comments on next page.

1B. ENROLLMENT REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Females Enrolled	10,152,589	9,397,957	92.6%	754,632	7.4%
%	58.2%	58.1%		59.5%	
Males Enrolled	6,887,791	6,389,817	92.8%	497,974	7.2%
%	39.5%	39.5%		39.3%	
Sex of Subjects is Unknown	408,078	392,814	96.3%	15,264	3.7%
%	2.3%	2.4%		1.2%	
Total Subjects Enrolled	**17,448,458**	**16,180,588**	92.7%	**1,267,870**	7.3%
%	100.0%	100.0%		100.0%	

See Table 1B comments on next page.

1C. MINORITY ENROLLMENT REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Minority Total**	**5,216,434**	**4,283,738**	82.1%	**932,696**	17.9%
% Minority Enrollment	**29.9%**	**26.5%**		73.6%	

See Table 1C comments on next page.

* Clinical research studies include non-intervention clinical research, clinical trials, epidemiologic studies, behavioral studies, database studies, etc., based on the NIH definition of clinical research. "Total All Clinical Studies" includes NIH Defined Phase III Clinical Trials.

** See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

COMMENTS

Table 1. Summary of NIH Clinical Research Reported in FY2007: Total Number of Protocols and Enrollment by Sex and Domestic versus Foreign Protocols

Table 1A: Total Number of Protocols

1. The total number of protocols reported in the NIH database in FY2007 was 15,567; of these, 10,914 (70.1%) reported subject enrollment. Of these, the remainder are new clinical studies or studies pending enrollment.
2. Subsequent tables reporting "Enrollment Reported" are based on the 10,914 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting "Enrollment Reported."

Total Domestic Protocols

4. Domestic protocols made up the vast majority of protocols (14,846; 95.4%); of these, 10,463 (70.5%) reported domestic subject enrollment.
5. Clinical research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Total Foreign Protocols

6. Foreign protocols account for only a small percentage of protocols 721 (4.6%); of these, 451 (62.6%) reported foreign subject enrollment.

Table 1B: Total Enrollment Reported

1. The total "Enrollment Reported" in the NIH database in FY2007 was 17,448,458 subjects in 10,914 protocols with enrollment.
2. Females made up 58.2% (10.2M) of total subjects enrolled, while Males made up 39.5% (6.9M), with 2.3% unknown.
3. Total Enrollment Reported increased by 18% in the past year (14,830,930 in FY2006; 17,448,458 in FY2007).

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 16,180,588 (92.7%)
5. Females made up 58.1% (9.4M) of the domestic subjects enrolled, while Males made up 39.5% (6.4M) with 2.4% (0.4M) unknown.

Total Foreign Enrollment

6. The total Foreign Enrollment reported was 1,267,870 (7.3%).
7. Females made up 59.5% (0.75M) of the foreign subjects enrolled, while males made up 39.3% (0.50M) with 1.2% unknown (0.015M).

Table 1C: Minority Enrollment Reported

1. Minorities made up 29.9% (5.2M) of the total subjects enrolled.
2. Minorities made up 26.5% (4.3M) of the total Domestic Enrollment.
3. Minority Enrollment Reported decreased 18% in the past year (6,388,316 in FY2006; 5,216,434 in FY2007). The small percentage of foreign protocols (4.1%) account for 17.9% of minority enrollment.

Table 2. Overview of NIH Extramural and Intramural Clinical Research Reported in FY2007: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

			Domestic				Foreign			
2A. PROTOCOLS REPORTED		**Total All Clinical Studies**	**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
Number of Protocols reporting females only		1,340	1,161	86.6%	127	9.5%	46	3.4%	6	0.4%
%		8.6%	8.9%		7.2%		7.3%		6.9%	
Number of Protocols reporting males only		517	470	90.9%	27	5.2%	15	2.9%	5	1.0%
%		3.3%	3.6%		1.5%		2.4%		5.7%	
Number of Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)		9,057	7,351	81.2%	1,327	14.7%	319	3.5%	60	0.7%
%		58.2%	56.2%		75.4%		50.3%		69.0%	
Total Number of Protocols with Enrollment		**10,914**	**8,982**	82.3%	**1,481**	13.6%	**380**	3.5%	**71**	0.7%
%		70.1%	69%		84.1%		59.9%		81.6%	
Number of Protocols with zero enrollment. Enrollment data has not yet been submitted.		4,653	4,103	88.2%	280	6.0%	254	5.5%	16	0.3%
%		29.9%	31.4%		15.9%		40.1%		18.4%	
Total Number of Protocols		**15,567**	**13,085**	84.1%	**1,761**	11.3%	**634**	4.1%	**87**	0.6%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

See Table 2A comments on next page.

			Domestic				Foreign			
2B. ENROLLMENT REPORTED		**Total All Clinical Studies**	**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
In Protocols reporting females only		9,000,648	6,830,795	75.9%	1,884,141	20.9%	142,737	1.6%	142,975	1.6%
%		51.6%	52.2%		60.8%		15.7%		40.1%	
In Protocols reporting males only		377,803	335,655	88.8%	3,203	0.8%	11,998	3.2%	26,947	7.1%
%		2.2%	2.6%		0.1%		1.3%		7.5%	
In Protocols excluding female-only and male-only enrollment protocols		8,070,007	5,913,901	73.3%	1,212,893	15.0%	756,196	9.4%	187,017	2.3%
%		46.3%	45.2%		39.1%		83.0%		52.4%	
Enrollment Totals for all studies		**17,448,458**	**13,080,351**	75.0%	**3,100,237**	17.8%	**910,931**	5.2%	**356,939**	2.0%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

See Table 2B Comments on next page.

			Domestic				Foreign			
2C. MINORITY ENROLLMENT REPORTED**			**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
Minority Totals for all studies		**5,216,434**	**3,651,722**	70.0%	**632,016**	12.1%	**746,278**	14.3%	**186,418**	3.6%
% Minority enrollment		29.9%	27.9%		20.4%		81.9%		52.2%	

See Table 2C comments on next page.

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

COMMENTS

Table 2: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2006: Number of Sex-Specific Protocols and Domestic versus Foreign Protocols

Table 2A: Total Number of Protocols with Enrollment

1. Female Only Protocols: There were 1,340 protocols reporting females only, representing 12.3% (1,340/10,914) of protocols with enrollment.
1,207 (90.1%) were Extramural Protocols; 132 (9.9%) were NIH Intramural Protocols.
1,288 (96.1%) were Domestic Protocols; 52 (3.9%) were Foreign Protocols.

2. Male Only Protocols: There were 517 protocols reporting males only, representing 4.7% (516/10,914) of protocols with enrollment.
485 (93.8%) were Extramural Protocols; 32 (6.2%) were NIH Intramural Protocols.
497 (96.1%) were Domestic Protocols; 20 (3.9%) were Foreign Protocols.

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 9,057 protocols reporting both female and male participants representing 83.0% (9,057/10,914) of protocols with enrollment.
7,760 (84.7%) were Extramural protocols; 1,384 (15.3%) were NIH Intramural protocols
8,678 (95.8%) were Domestic Protocols; 379 (4.2%) were Foreign Protocols.

Table 2B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 9.0 M females, representing 51.6% of total enrollment
7.0M (77.5%) were in Extramural protocols; 2.03 (22.5%) were in NIH Intramural protocols.
8.7M (96.8%) were Domestic protocols, 0.28 (3.2%) were Foreign Protocols.

2. In Male Only Protocols: There were approximately 377,803 males, representing 2.2% of total enrollment
0.35M (92.0%) were in Extramural protocols; 0.3 (8.0%) were in NIH Intramural protocols.
0.34M (89.7%) were Domestic protocols; 0.38M (10.3%) were Foreign protocols.

3. In Protocols reporting Both Females and Males (excluding sex-specific studies): There were approximately 8.1M subjects, representing 46.3% of total enrollment
6.6M (82.7%) were in Extramural protocols; 1.4M (17.3%) were in NIH Intramural protocols.
7.13M (88.3%) were Domestic protocols, 0.94M (11.7%) were Foreign protocols.

Table 2C Minority Enrollment Reported

Total Minority Enrollment: 29.9% of Total Enrollment (5.2M/17.4M)
Total Domestic Minority Enrollment: 4.3M (82.1%) of Total Minority Enrollment (4,283,738/5,216,434).
Total Foreign Minority Enrollment: 0.93M (17.9%) of Total Minority Enrollment (932,696/5,216,434).

Total Domestic Minority Enrollment (Extramural + Intramural): 4.3M (24.6%) of Total Enrollment (4,283,738/17,448,458).
Total Foreign Minority Enrollment (Extramural + Intramural): 0.93M (5.3%) of Total Enrollment (932,696/17,448,458).

Total Minority Enrollment in all Extramural protocols (Domestic + Foreign): 4.4M (25.2%) of Total Enrollment (4,398,000/17,448,458).

Total Minority Enrollment in all Intramural protocols (Domestic + Foreign): 0.82M (4.7%) of Total Enrollment (818,434/17,448,458).

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2007: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

3A. PROTOCOLS REPORTED	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Protocols with Enrollment	653	609	93.3%	44	6.7%
%	87.2%	87.6%		81.5%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	96	86	89.6%	10	10.4%
	12.8%	12.4%		18.5%	
Total Number of Protocols	**749**	**695**	92.8%	**54**	7.2%
%	100.0%	100.0%		100.0%	

See Table 3A comments on next page.

3B. ENROLLMENT REPORTED	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Females Enrolled	324,694	228,289	70.3%	96,405	29.7%
%	54.9%	53.3%		59.2%	
Males Enrolled	249,633	183,878	73.7%	65,755	26.3%
%	42.2%	42.9%		40.4%	
Sex of Subjects is Unknown	16,832	16,273	96.7%	559	0.0%
%	2.8%	3.8%		0.3%	
Total Subjects Enrolled	**591,159**	**428,440**	72.5%	**162,719**	27.5%
%	100.0%	100.0%		100.0%	

See Table 3B comments on next page.

3C. MINORITY ENROLLMENT REPORTED**	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Minority Total for all Phase III studies	**244,932**	**88,339**	36.1%	**156,593**	63.9%
	41.4%	20.6%		96.2%	

See Table 3C on next page.

* An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

COMMENTS

Table 3. Summary of NIH Phase III Clinical Research Reported in FY2007: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

Table 3A: Total Number of Protocols

1. The total number of NIH defined Phase III Clinical Protocols reported in the NIH database in FY2007 was 749; of these, 653 (87.2%) reported subject enrollment. Of these, the remainder are new clinical studies or studies pending enrollment.

2. Subsequent tables reporting "Enrollment Reported" are based on the 653 protocols reporting subject enrollment, or a defined subset.

3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting "Enrollment Reported"

Total Domestic Protocols:

4. Domestic protocols made up the majority of protocols with a total of 695 (92.8%); of these, 609 (87.6%) reported domestic subject enrollment.

5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Total Foreign Protocols

6. Total Foreign Protocols accounted for only a small percentage of protocols 54 (7.2%). Of these, 44 (6.7%) reported foreign enrollment.

Table 3B: Total Enrollment Reported

1. The total "Enrollment Reported" in NIH Defined Phase III Protocols in the NIH database in FY2007 was 591,159 subjects in 653 protocols.

2. Females 324,649 made up (54.9%) of the total subjects enrolled, while Males 249,633 made up (42.2%) with Unknowns 16,832 making up (2.8%).

3. Minorities 244,932 made up (41.4%) of the total subjects enrolled 591,159.

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 428,440 (72.5%).

5. Females 228,289 made up (53.3%) of the Domestic subjects enrolled, while Males 183,878 made up 42.9% with Unkowns 16,273 making up (3.8%).

Total Foreign Enrollment Reported

6. The total Foreign Enrollment Reported was 162,719 (27.5%).
7. Females 96,405 made up (59.2%) of the Foreign subjects enrolled, while Males 65,755 made up (40.4%), with Unknowns 559 making up (0.3%).
8. Total Foreign Enrollment increased by 64% from 99,133 in FY2006 to 162,719 in FY 2007).

Table 3C: Minority Enrollment Reported

1. Total Minority Enrollment was 41.4% (244,932) of Total Enrollment Reported 591,159.
2. Minorities 88,339 made up (20.6%) of the Total Domestic Enrollment 428,440.
3. Minorities 156,593 made up (96.2%) of the Total Foreign Enrollment 162,719.
4. Total Minority Enrollment 88,339 was (36.1%) Domestic 156,593 and (63.9%) Foreign.

Table 4. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2007: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

			Domestic				Foreign			
4A. PROTOCOLS REPORTED		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Protocols reporting female only		121	111	91.7%	4	3.3%	5	4.1%	1	0.8%
%		16.2%	16.8%		11.8%		10.0%		25.0%	
Protocols reporting male only		41	40	97.6%	0	0.0%	1	2.4%	0	0.0%
%		5.5%	6.1%		0.0%		2.0%		0.0%	
Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)		491	426	86.8%	28	5.7%	34	6.9%	3	0.6%
%		65.6%	64.4%		82.4%		68.0%		75.0%	
Total Number of Protocols with Enrollment		**653**	**577**	88.4%	**32**	4.9%	**40**	6.1%	**4**	0.6%
%		87.2%	87%		94.1%		80.0%		100.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.		96	84	87.5%	2	2.1%	10	10.4%	0	0.0%
%		12.8%	12.7%		5.9%		20.0%		0.0%	
Total Number of Phase III Protocols		**749**	**661**	88.3%	**34**	4.5%	**50**	6.7%	**4**	0.5%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

See Table 4A comments on next page.

			Domestic				Foreign			
4B. ENROLLMENT REPORTED		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Protocols reporting female only		181,625	144,902	79.8%	7	0.0%	29,707	16.4%	7,009	3.9%
%		30.7%	36.7%		0.0%		19.4%		70.3%	
Protocols reporting male only		79,434	76,650	96.5%	0	0.0%	2,784	3.5%	0	0.0%
%		13.4%	19.4%		0.0%		1.8%		0.0%	
Protocols excluding female-only and men-only enrollment protocols		330,100	173,384	52.5%	33,497	10.1%	120,260	36.4%	2,959	0.9%
%		55.8%	43.9%		100.0%		78.7%		29.7%	
Total Subjects Enrolled		**591,159**	**394,936**	66.8%	**33,504**	5.67%	**152,751**	25.84%	**9,968**	1.7%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

See Table 4B comments on next page.

			Domestic				Foreign			
4C. MINORITY ENROLLMENT REPORTED**		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Minority Total for all Phase III studie		**244,932**	**83,634**	34.1%	**4,705**	1.9%	**149,424**	61.0%	**7,169**	2.9%
%		41.4%	21.2%		14.0%		97.8%		71.9%	

See Table 4C comments on next page.

* An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may

COMMENTS

Table 4. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported in FY 2007: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign

Table 2A: Total Number of Protocols with Enrollment

1. Female Only Protocols: There were 121 protocols reporting females only, representing 18.5% of protocols with enrollment.

116 (95.8%) were Extramural Protocols; 5 (3.4%) were NIH Intramural Protocols.
40 (97.6%) were Domestic Protocols; 1 (2.4%) were Foreign Protocols.

2. Male Only Protocols: There were 41 protocols reporting males only, representing 0.6% of protocols with enrollment.

41 (100%) were Extramural Protocols; there were no NIH Intramural Protocols.
40 (97.6%) were Domestic Protocols; 1 (2.4%)3.9% were Foreign Protocols.

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 491 protocols reporting both female and male participants representing 75.2% of protocols with enrollment.

460 (93.7%) were Extramural protocols; 31 (6.3%) were NIH Intramural projects.
454 (92.5%) were Domestic Protocols; 36 (7.5% were Foreign Protocols.

Table 2B Total Enrollment Reported

1. In Female Only Protocols: There were 181,625 females, representing 30.7% of total enrollment

174,609 (96.2%) were in Extramural protocols; 7,016 (3.9%) were in NIH Intramural protocols.
144,909 (79.8%) were Domestic protocols, 36,716 (20.3%) were Foreign protocols.

2. In Male Only Protocols: There were approximately 377,803 males, representing 2.2% of total enrollment

79,434 (100%) were in Extramural protocols; there were no NIH Intramural protocols.
76,650 (96.5%) were Domestic protocols; 2,784 (3.5%) were Foreign protocols.

3. In Protocols reporting Both Females and Males (excluding sex-specific studies): There were 330,100 subjects, representing 5.1% of total enrollment

293,644 (88.9%) were in Extramural protocols; 36,456 (11%) were in NIH Intramural protocols.
206,881 (62.6%) were Domestic protocols, 123,219 (36.4%) were Foreign protocols.

Table 2C Minority Enrollment Reported

Total Minority Enrollment: 41% of Total Enrollment (244,932/591,159)
Total Domestic Minority Enrollment: 36%% of Minority Enrollment (88,339/244,932).
Total Foreign Minority Enrollment: 63%% of Minority Enrollment (156,593/244,932).

Total Domestic Minority Enrollment (Extramural + Intramural): 15% of Total Enrollment (88,339/591,159))
Total Foreign Minority Enrollment (Extramural + Intramural): 26%% of Total Enrollment (156,593/591,159).

Total Minority Enrollment in all Extramural projects (Domestic + Foreign): 39%% of Total Enrollment (233,058/591,159).
Total Minority Enrollment in all Intramural projects (Domestic + Foreign): 2% of Total Enrollment (11,874/591,159).

Table 5. NIH Thirteen Year Trends for Protocol and Enrollment Data: 1995-2007*

5A Part I. Thirteen Year Increases in Protocols and Enrollment Data

FY Reported	1995		2007	Relative Increase, 2007 / 1995
Total Protocols with Enrollment	**3,188**		**10,914**	**3.4**
Total Enrollment	**1,021,493**		**17,448,458**	**17.1**
Total Minorities	**374,433**		**5,216,434**	**13.9**
% of Minority	**36.7%**		**29.9%**	**0.8**

5A Part II. Six Year Increases in Protocols and Enrollment Data: Foreign and Domestic

FY Reported	2002		2007	Relative Increase, 2007 / 1995
Total DOMESTIC Enrollment data	**10,192,401**		**16,180,588**	**1.6**
Total FOREIGN Enrollment	**946,083**		**1,267,870**	**1.3**

Table 5A Comments:

1. There was a 3.4 fold increase in protocols with enrollment reported from 1995 to 2007, from 3,188 protocols to 10,914 protocols.

2. There was a 17.1 fold increase in enrollment reported from 1995 to 2007, from approximately 1M to 17M.

3. There was a 13.9 fold increase in minority enrollment from 1995 to 2007, from approximately 0.4M to 5M.

4. Domestic and Foreign data were reported for FY 2002-2007, showed a 1.6 fold increase in domestic enrollment (from 10.2M to 16M) and a 1.3 fold increase in foreign enrollment (from 0.95M to 1.2M).

5. See Table 6 for 13 year enrollment totals 1995-2007.

*NOTE: Trend data varies 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.
NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

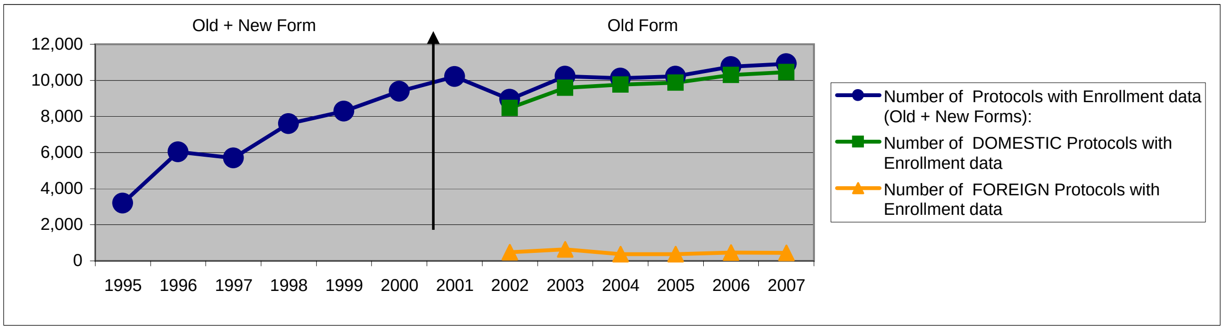
Table 5. NIH Thirteen Year Trends for Protocol and Enrollment Data: 1995-2007*

5B. Thirteen Year Summary of Total Number of Protocols Reported: FY 1995-2007

FY Reported	FY Funded	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols with Enrollment data	Number of FOREIGN Protocols with Enrollment data	Percent Domestic Protocols	Protocol Form*
1995	1994	3,188				Old
1996	1995	6,036				
1997	1996	5,692				
1998	1997	7,602				
1999	1998	8,285				
2000	1999	9,390				
2001	2000	10,212				
2002	2001	8,945	8,463	482	94.6%	Old + New
2003	2002	10,216	9,578	638	93.8%	
2004	2003	10,125	9,760	365	96.4%	
2005	2004	10,233	9,862	371	96.4%	
2006	2005	10,758	10,294	464	95.7%	
2007	2006	10,914	10,463	451	95.9%	

Table 5B Comments:

Total Protocols by Year Reported



1. Table 5B and 5B Graph provide the number of OLD and NEW protocols year by year (1995-2007) and the distribution between domestic and foreign protocols for years 2002-2007.

2. The total number of protocols reported with enrollment have leveled off at about 10,000 over the last 6 years.

3. The vast majority of protocols were for domestic studies for 2002-2007, ranging from 93.8% to 96.4% of protocols.

* Data have been reported using a combined race/ethnicity format (OLD FORM) since 1995. New protocols began reporting separate race and ethnicity data in FY2002 (NEW FORM). During 2002-2007, data have been reported using both Old and New Forms.

*See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

Table 5. NIH Thirteen Year Trends for Protocol and Enrollment Data: 1995-2007*

5C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2007

FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC Enrollment data	Percent DOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGN Enrollment
2002	2001	11,138,484	10,192,401	91.5%	946,083	8.5%
2003	2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%
2004	2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%
2005	2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%
2006	2005	14,830,930	11,425,701	77.0%	3,405,229	23.0%
2007	2006	17,448,458	16,180,588	92.7%	1,267,870	7.3%

Percent Comparison of Domestic and Foreign Enrolment

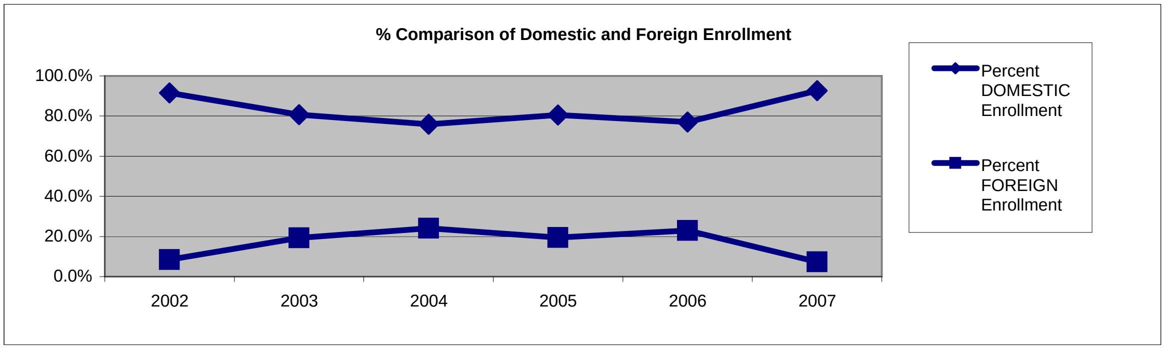


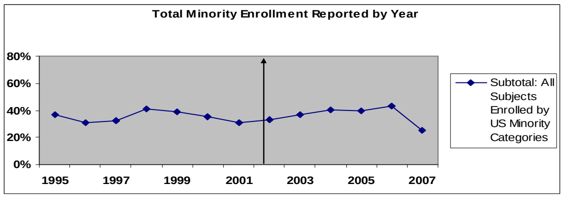
Table 5C Comments:

1. Overall total enrollment has increased, as well as total domestic and foreign enrollment during the last 6 years.
2. The percentage of foreign enrollment has decreased to approximately 7.3% in FY 2007 as domestic enrollment increased to 92.7%.

Table 6. NIH Thirteen Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2007: Enrollment by Race and Ethnicity

6A. Thirteen YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER AND MINORITY CATEGORIES IN ALL PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Form	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms):
1995	1994	Old	528,421	459,921	33,151	1,021,493	374,433	3,188
	%		51.7%	45.0%	3.2%	100.0%	36.7%	
1996	1995	Old	4,130,385	2,583,865	91,054	6,805,304	2,125,958	6,036
	%		60.7%	38.0%	1.3%	100.0%	31.2%	
1997	1996	Old	3,320,610	1,930,783	65,540	5,316,933	1,709,223	5,692
	%		62.5%	36.3%	1.2%	100.0%	32.2%	
1998	1997	Old	4,246,130	2,716,880	115,566	7,078,576	2,923,662	7,602
	%		60.0%	38.4%	1.6%	100.0%	41.3%	
1999	1998	Old	5,102,306	2,712,068	169,863	7,984,237	3,108,228	8,285
	%		63.9%	34.0%	2.1%	100.0%	38.9%	
2000	1999	Old	5,585,042	3,919,065	64,990	9,569,097	3,406,297	9,390
	%		58.4%	41.0%	0.7%	100.0%	35.6%	
2001	2000	Old	6,808,822	4,740,887	44,547	11,594,256	3,619,119	10,212
	%		58.7%	40.9%	0.4%	100.0%	31.1%	
2002	2001	Old + New	7,155,549	3,904,560	78,375	11,138,484	3,666,880	8,945
	%		64.2%	35.1%	0.7%	100%	32.9%	
2003	2002	Old + New	8,514,481	6,121,496	136,277	14,772,254	5,387,692	10,216
	%		57.6%	41.4%	0.9%	100.0%	36.5%	
2004	2003	Old + New	10,889,097	7,741,892	292,931	18,923,920	7,611,611	10,125
	%		57.5%	40.9%	1.5%	100.0%	40.2%	
2005	2004	Old + New	9,503,922	5,941,907	276,923	15,722,752	6,245,436	10,233
			60.4%	37.8%	1.8%	100.0%	39.7%	
2006	2005	Old + New	9,473,273	5,172,205	185,452	14,830,930	6,388,316	10,758
			63.9%	34.9%	1.25%	100.0%	43.1%	
2007	2006	Old + New	10,152,590	6,887,793	408,075	17,448,458	5,216,890	10,914
			58.2%	39.5%	2.34%	100.0%	29.9%	



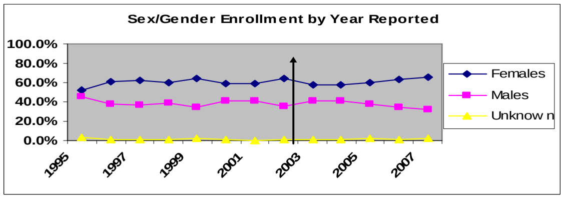


Table 6A Comments:

1. Table 6A summarizes enrollment by sex/gender and minority race/ethnicity categories for the Thirteen year reporting period (1995-2007). The data are compiled from Tables 6B, 6C and 6D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 6B) and the NEW Enrollment Form (Tables 6C and 6D).

2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because th categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.
NOTE: Trend data varies 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; (3) and the subtraction of studies that are no longer reported.

Table 6. NIH Thirteen Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2007: Enrollment by Race and Ethnicity

Notes Tables B-D

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 6B, 6C and 6D are combined to provide the summary data in Table 6A.

6B. OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/Other		Total	Subtotal Using US Minority Categories (shaded): OLD FORM		Number Protocols with Enrollment data (Old Form):
1995	**1994**	11,221	38,952	234,976	89,284	540,313	106,747		**1,021,493**	**374,433**		**3,188**
	%	1.1%	3.8%	23.0%	8.7%	52.9%	10.5%		100.0%	36.7%		
1996	**1995**	146,319	617,211	823,102	539,326	4,114,249	565,097		**6,805,304**	**2,125,958**		**6,036**
	%	2.2%	9.1%	12.1%	7.9%	60.5%	8.3%		100.0%	31.2%		
1997	**1996**	36,638	321,479	864,102	487,004	3,199,778	407,932		**5,316,933**	**1,709,223**		**5,692**
	%	0.7%	6.0%	16.3%	9.2%	60.2%	7.7%		100.0%	32.1%		
1998	**1997**	85,957	1,237,030	1,096,218	504,457	3,713,759	441,155		**7,078,576**	**2,923,662**		**7,602**
	%	1.2%	17.5%	15.5%	7.1%	52.5%	6.2%		100.0%	41.3%		
1999	**1998**	71,436	1,429,022	1,081,210	526,560	4,470,966	405,043		**7,984,237**	**3,108,228**		**8,285**
	%	0.9%	17.9%	13.5%	6.6%	56.0%	5.1%		100.0%	38.9%		
2000	**1999**	82,728	1,525,392	1,209,769	588,408	5,588,942	573,858		**9,569,097**	**3,406,297**		**9,390**
	%	0.9%	15.9%	12.6%	6.1%	58.4%	6.0%		100.0%	35.6%		
2001	**2000**	105,067	1,495,279	1,199,625	819,148	7,314,449	660,688		**11,594,256**	**3,619,119**		**10,212**
	%	0.9%	12.9%	10.3%	7.1%	63.1%	5.7%		100.0%	31.2%		
2002	**2001**	45,843	1,222,296	702,234	398,657	4,044,052	321,349		**6,734,431**	**2,369,030**		**6,187**
	%	0.7%	18.1%	10.4%	5.9%	60.1%	4.8%		100.0%	35.2%		
2003	**2002**	36,579	730,542	472,426	288,523	3,238,284	278,901		**5,045,255**	**1,528,070**		**4,903**
	%	0.7%	14.5%	9.4%	5.7%	64.2%	5.5%		100.0%	30.3%		
2004	**2003**	29,387	307,052	342,188	214,322	2,348,529	172,130		**3,413,608**	**892,949**		**2,782**
	%	0.9%	9.0%	10.0%	6.3%	68.8%	5.0%		100.0%	26.2%		
2005	**2004**	22,375	254,598	229,615	134,972	1,267,089	102,405		**2,011,054**	**641,560**		**1,786**
	%	1.1%	12.7%	11.4%	6.7%	63.0%	5.1%		100.0%	31.9%		
2006	**2005**	19,648	131,786	148,948	78,596	883,041	63,231		**1,325,250**	**378,978**		**1,391**
	%	1.5%	9.9%	11.2%	5.9%	66.6%	4.8%		100.0%	28.6%		
2007	**2006**	5,372	51,742	238,004	83,192	1,097,387	48,630		**1,524,327**	**378,310**		**1,098**
	%	0.4%	3.4%	15.6%	5.5%	72.0%	3.2%		100.0%	24.8%		

ORIENTATION TO TABLES 6C and 6D.

1. The New Form consists of Parts A and B (Tables 6C and 6D) for reporting years 2002-2007. This Form is provided as part of the annual progress report.
2. Table 6C displays the New Form Part A for reporting separate race and ethnicity data.

3. Table 6D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the "Hispanic or Latino" column in Part A.

6C. New Form Part A: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats

Total of All Subjects by Race									Total of All Subjects by Ethnicity			
FY Reported	**FY Funded**	**American Indian/ Alaska Native**	**Asian**	**Black or African American**	**Hawaiian /Pacific Islander**	**White**	**More Than One Race**	**Unknown /Other**	**Total***	**Not Hispanic**	**Hispanic or Latino****	**Unknown /Not Reported**	**Total***
2002	**2001**	77,734	354,049	547,776	21,636	2,651,541	30,955	720,362	**4,404,053**	3,071,952	292,429	1,039,672	**4,404,053**
	%	1.8%	8.0%	12.4%	0.5%	60.2%	0.7%	16.4%	100.0%	69.8%	6.6%	23.6%	100.0%
2003	**2002**	63,544	2,138,002	960,090	37,569	5,415,710	99,462	1,012,622	**9,726,999**	8,162,259	611,641	953,099	**9,726,999**
	%	0.7%	22.0%	9.9%	0.4%	55.7%	1.0%	10.4%	100.0%	83.9%	6.3%	9.8%	100.0%
2004	**2003**	98,047	4,345,396	1,379,857	54,452	8,065,069	186,241	1,381,250	**15,510,312**	13,168,842	756,339	1,585,131	**15,510,312**
	%	0.6%	28.0%	8.9%	0.4%	52.0%	1.2%	8.9%	100.0%	84.9%	4.9%	10.2%	100.0%
2005	**2004**	292,215	3,046,370	1,358,262	53,286	7,672,890	182,953	1,105,722	**13,711,698**	11,804,164	773,939	1,133,595	**13,711,698**
	%	2.1%	22.2%	9.9%	0.4%	56.0%	1.3%	8.1%	100.0%	86.1%	5.6%	8.3%	100.0%
2006	**2005**	141,567	3,463,202	1,251,339	38,460	7,089,017	321,554	1,200,541	**13,505,680**	11,308,244	1,054,313	1,143,123	**13,505,680**
	%	1.0%	25.6%	9.3%	0.3%	52.5%	2.4%	8.9%	100.0%	83.7%	7.8%	8.5%	100.0%
2007	**2006**	145,417	1,356,900	2,012,695	57,149	10,341,483	278,068	1,732,419	**15,924,131**	13,017,124	1,169,092	1,737,915	**15,924,131**
	%	0.9%	8.5%	12.6%	0.4%	64.9%	1.7%	10.9%	100.0%	81.7%	7.3%	10.9%	100.0%

6D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown/Other	Total Hispanic or Latino**	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Protocols with Enrollment data (New Form):
2002	**2001**	4,867	1,305	13,066	101	159,252	7390	106,448	**292,429**	**1,297,850**		**2,758**
	%	1.7%	0.4%	4.5%	0.0%	54.5%	2.5%	36.4%	100.0%	29.5%		
2003	**2002**	5,400	1,953	14,566	679	350,439	28,088	210,516	**611,641**	**3,859,622**		**5,313**
	%	0.9%	0.3%	2.4%	0.1%	57.3%	4.6%	34.4%	100.0%	39.7%		
2004	**2003**	6,408	5,040	25,276	2,037	361,112	62,909	293,557	**756,339**	**6,718,662**		**7,343**
	%	0.8%	0.7%	3.3%	0.3%	47.7%	8.3%	38.8%	100.0%	43.3%		
2005	**2004**	22,739	7,816	19,446	1,981	388,874	51,166	281,916	**773,938**	**5,603,876**		**8,447**
	%	2.9%	1.0%	2.5%	0.3%	50.2%	6.6%	36.4%	100.0%	40.9%		
2006	**2005**	45,074	6,641	21,712	2,193	417,495	185,477	375,721	**1,054,313**	**6,009,338**		**9,367**
	%	4.3%	0.6%	2.1%	0.2%	39.6%	17.6%	35.6%	100.0%	44.5%		
2007	**2006**	37,581	7,414	31,239	4,310	538,216	100,197	450,135	**1,169,092**	**4,838,580**		**9,816**
	%	3.2%	0.6%	2.7%	0.4%	46.0%	8.6%	38.5%	100.0%	30.4%		

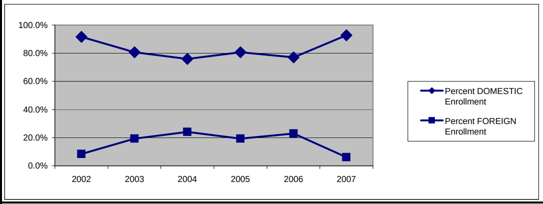
*** These totals must agree.**

****These totals must agree.**

Table 6. NIH Thirteen Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2007: Enrollment by Race and Ethnicity

6E. Comparison of Domestic and Foreign Enrollment & Protocols with Total Enrollment for the period FY2002-2007

		ENROLLMENT					PROTOCOLS				
FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC Enrollment	Percent DOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGN Enrollment	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols	Percent Domestic Protocols	Number of FOREIGN Protocols	Percent Foreign Protocols
2002	2001	11,138,484	10,192,401	91.5%	946,083	8.5%	8,945	8,463	94.6%	482	5.4%
2003	2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%	10,216	9,578	93.8%	638	6.2%
2004	2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%	10,125	9,760	96.4%	365	3.6%
2005	2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%	10,233	9,862	96.4%	371	3.6%
2006	2005	14,830,930	11,425,701	77.0%	3,405,229	23.0%	10,758	10,294	95.7%	464	4.3%
2007	2006	17,448,458	16,180,588	92.7%	1,267,870	6.1%	10,914	10,463	95.9%	451	4.1%



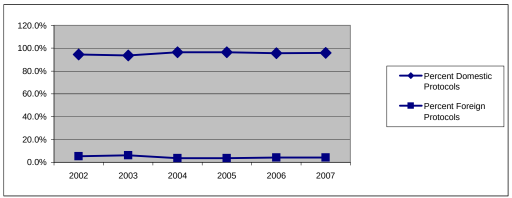


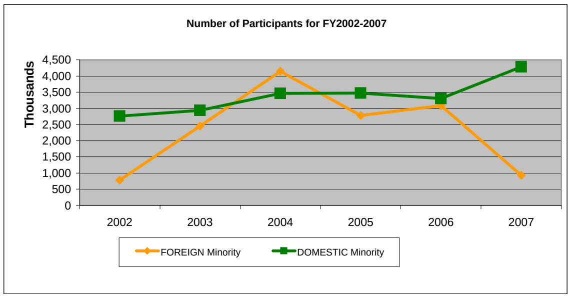
Table 6 E Comments:

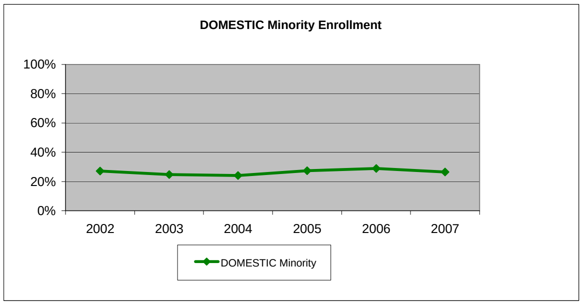
1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2007.
2. The Domestic enrollment increased to approximately 93%, while the Foreign enrollment decreased to approximately 6.1%.

3. The vast majority of protocols are domestic protocols (approximately 94-96%), while foreign protocols make up approximately 4-6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

6F. Comparison of Domestic and Foreign Minority Participation for FY 2002-2007

FY Reported	FY Funded	FOREIGN Minority	Foreign Total	DOMESTIC Minority	Domestic Total
2002	2001	777,461	946,083	2,754,820	10,149,869
		82.2%	100.0%	27.1%	100.0%
2003	2002	2,452,329	2,860,897	2,935,363	11,911,357
		85.7%	100.0%	24.6%	100.0%
2004	2003	4,147,255	4,564,127	3,464,356	14,359,793
		90.9%	100.0%	24.1%	100.0%
2005	2004	2,776,565	3,052,894	3,468,864	12,669,858
		90.9%	100.0%	27.4%	100.0%
2006	2005	3,087,181	3,405,229	3,301,135	11,425,701
		90.7%	100.0%	28.9%	100.0%
2007	2006	932,686	1,267,870	4,283,738	16,180,588
		73.6%	100.0%	26.5%	100.0%





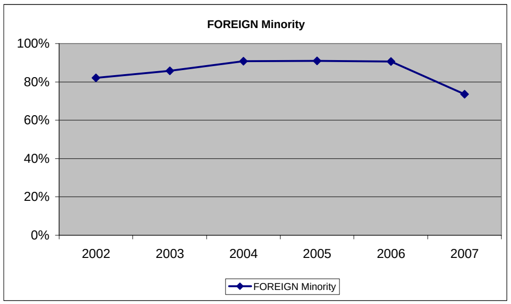


Table 6F Comments:

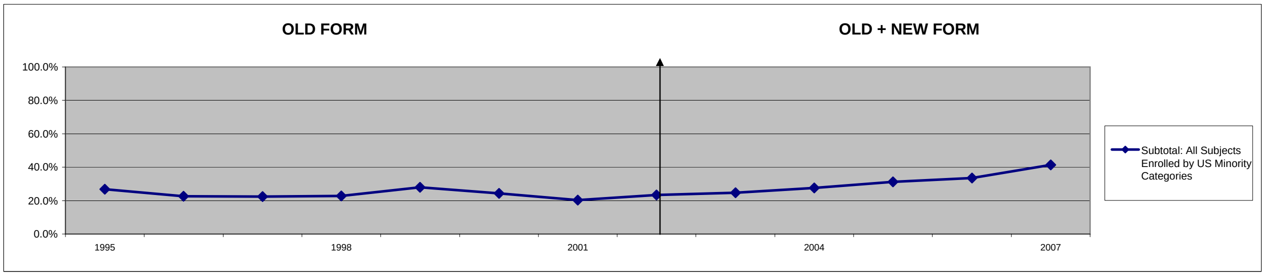
1. Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment.
2. Foreign Minority Enrollment has varied from 73.6% to 90.9% of Total Foreign Enrollment, reflecting that most of the foreign research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary minority data used in this report.

Table 7: Thirteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2007: Enrollment by Race and Ethnicity

7A. Phase III Thirteen YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER IN ALL PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms):
1995	1994	171,181	108,324	19,818	299,323	80,562	560
	%	57.2%	36.2%	6.6%	100.0%	26.9%	
1996	1995	264,755	203,698	21,210	489,663	110,669	608
	%	54.1%	41.6%	4.3%	100.0%	22.6%	
1997	1996	264,755	203,698	21,210	489,663	110,000	608
	%	54.1%	41.6%	4.3%	100.0%	22.5%	
1998	1997	228,417	74,389	2,705	305,511	69,599	320
	%	74.8%	24.3%	0.9%	100.0%	22.8%	
1999	1998	339,533	163,950	1,446	504,929	141,449	578
	%	67.2%	32.5%	0.3%	100.0%	28.0%	
2000	1999	313,952	180,705	1,086	495,743	120,339	589
	%	63.3%	36.5%	0.2%	100.0%	24.3%	
2001	2000	412,379	168,085	1,273	581,737	117,873	645
	%	70.9%	28.9%	0.2%	100.0%	20.3%	
2002	2001	278,876	195,090	781	474,747	111,269	754
	%	58.7%	41.1%	0.2%	100.0%	23.4%	
2003	2002	294,950	239,403	1,914	536,267	132,302	852
	%	55.0%	44.6%	0.4%	100.0%	24.7%	
2004	2003	301,353	242,913	1,101	545,367	150,456	573
	%	55.3%	44.5%	0.2%	100.0%	27.6%	
2005	2004	290,977	197,300	4,723	493,000	154,191	547
		59.0%	40.0%	1.0%	100.0%	31.3%	
2006	2005	314,066	179,975	5,389	499,430	167,446	624
		62.9%	36.0%	1.1%	100.0%	33.5%	
2007	2006	324,694	249,633	16,832	591,159	244,932	621
		54.9%	42.2%	2.8%	100.0%	41.4%	

Total Phase III Enrollment by Year Reported



Sex/Gender Phase III Enrollment by Year Reported

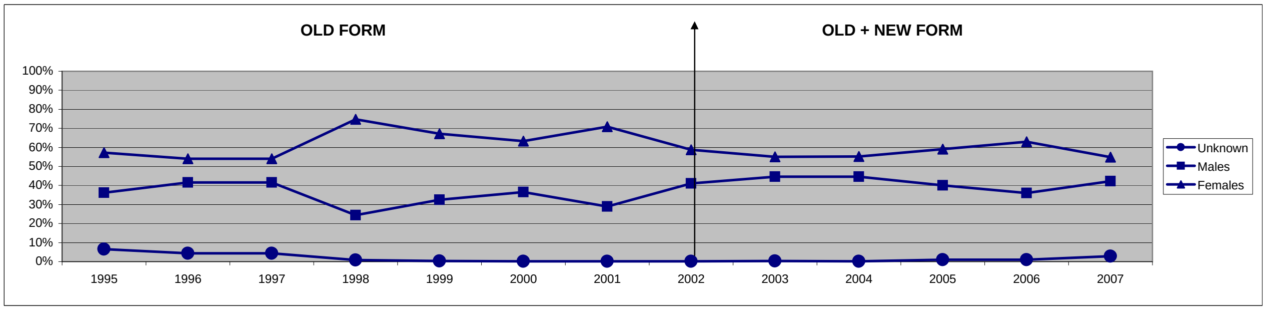


Table 7A Comments:

1. Table7A summarizes enrollment by sex/gender and minority race/ethnicity categories for the Thirteen year reporting period (1995-2007). The data are compiled from Tables 7B, 7C and 7D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 7B) and the NEW Enrollment Form (Tables 7C and 7D).

2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

NOTE: Trend data varies 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; (3) and the subtraction of studies that are no longer reported.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Table 7: Thirteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2007: Enrollment by Race and Ethnicity

Notes Tables 7B-D

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 7B, 7C and 7D are combined to provide the summary data in Table 7A.

7B. Phase III OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other		Total	Subtotal Using US Minority Categories (shaded): OLD FORM		Number Protocols with Enrollment data (Old Form):
1995	**1994**	5,358	2,740	52,433	20,031	172,773	45,988		299,323	80,562		560
	%	1.8%	0.9%	17.5%	6.7%	57.7%	15.4%		100.0%	26.9%		
1996	**1995**	4,235	40,126	46,838	19,470	321,445	57,549		489,663	110,669		608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%		100.0%	22.6%		
1997	**1996**	4,235	40,126	46,838	19,470	321,445	57,549		489,663	110,669		608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%		100.0%	22.6%		
1998	**1997**	5,030	5,324	42,805	16,440	229,534	6,378		305,511	69,599		320
	%	1.6%	1.7%	14.0%	5.4%	75.1%	2.1%		100.0%	22.8%		
1999	**1998**	3,685	20,276	76,921	40,567	336,703	26,777		504,929	141,449		578
	%	0.7%	4.0%	15.2%	8.0%	66.7%	5.3%		100.0%	28.0%		
2000	**1999**	3,726	24,017	62,512	30,084	335,824	39,580		495,743	120,339		589
	%	0.8%	4.8%	12.6%	6.1%	67.7%	8.0%		100.0%	24.3%		
2001	**2000**	4,079	11,132	70,110	32,552	422,802	41,062		581,737	117,873		645
	%	0.7%	1.9%	12.1%	5.6%	72.7%	7.1%		100.0%	20.3%		
2002	**2001**	1,645	20,560	51,991	29,636	315,543	12,228		431,603	103,832		**660**
	%	0.38%	4.8%	12.0%	6.9%	73.1%	2.8%		100.00%	24.1%		
2003	**2002**	1,689	20,038	49,255	29,066	337,654	16,615		454,317	100,048		**656**
	%	0.4%	4.4%	10.8%	6.4%	74.3%	3.7%		100.0%	22.0%		
2004	**2003**	1,505	18,807	45,285	32,974	265,764	14,050		378,385	98,571		**296**
	%	0.4%	5.0%	12.0%	8.7%	70.2%	3.7%		100.0%	26.1%		
2005	**2004**	1,319	17,740	39,402	21,829	231,492	4,507		316,289	80,290		**210**
	%	0.4%	5.6%	12.5%	6.9%	73.2%	1.4%		100.0%	25.4%		
2006	**2005**	1,012	16,800	20,355	9,524	175,724	6,348		229,763	47,691		**215**
	%	0.4%	7.3%	8.9%	4.1%	76.5%	2.8%		100.0%	20.8%		
2007	**2006**	751	3,943	21,582	9,333	169,789	4,259		209,657	35,609		**197**
	%	0.4%	1.9%	10.3%	4.5%	81.0%	2.0%		100.0%	17.0%		

ORIENTATION TO TABLES 7C and 7D.

1. The New Form consists of Parts A and B (Tables 7C and 7D) for reporting years 2002-2007. This Form is provided as part of the annual progress report.
2. Table 7C displays the New Form Part A for reporting separate race and ethnicity data.
3. Table 7D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the "Hispanic or Latino" column in Part A.

7C. Phase III New Form: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown/Not Reported	Total
2002	**2001**	159	799	4,647	52	34,654	560	2,273	43,144	36,224	1,629	5,291	43,144
	%	0.37%	1.85%	10.77%	0.12%	80.32%	1.30%	5.27%	100.00%	83.96%	3.78%	12.26%	100.00%
2003	**2002**	484	2,609	21,641	220	47,869	989	8,138	81,950	64,295	7,831	9,824	81,950
	%	0.6%	3.2%	26.4%	0.3%	58.4%	1.2%	9.9%	100.0%	78.5%	9.6%	12.0%	100.0%
2004	**2003**	1,396	4,385	43,721	611	106,793	4,419	5,657	166,982	145,742	13,435	7,805	166,982
	%	0.8%	2.6%	26.2%	0.4%	64.0%	2.6%	3.4%	100.0%	87.3%	8.0%	4.7%	100.0%
2005	**2004**	2,164	9,192	50,338	462	101,238	3,063	10,254	176,711	156,650	10,397	9,664	176,711
	%	1.2%	5.2%	28.5%	0.3%	57.3%	1.7%	5.8%	100.0%	88.6%	5.9%	5.5%	100.0%
2006	**2005**	4,630	32,360	50,780	535	126,670	4,246	50,446	269,667	202,358	31,034	36,275	269,667
	%	1.7%	12.0%	18.8%	0.2%	47.0%	1.6%	18.7%	100.0%	75.0%	11.5%	13.5%	100.0%
2007	**2006**	9,351	47,364	84,468	555	133,002	4,145	102,617	381,502	254,692	71,622	55,188	381,502
	%	2.5%	12.4%	22.1%	0.1%	34.9%	1.1%	26.9%	100.0%	66.8%	18.8%	14.5%	100.0%

7D. Phase III Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Protocols with Enrollment data (New Form):
2002	**2001**	49	22	31	4	660	304	560	1,630	**7,437**		**94**
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	17.2%		
2003	**2002**	37	70	186	23	2,115	203	5,197	7,831	**32,254**		**196**
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	39.4%		
2004	**2003**	269	59	193	26	7,264	3,052	2,572	13,435	**54,405**		**277**
	%	2.0%	0.4%	1.4%	0.2%	54.1%	22.7%	19.1%	100.0%	32.6%		
2005	**2004**	759	42	446	45	3,667	423	5,015	10,397	**73,901**		**337**
	%	7.3%	0.4%	4.3%	0.4%	35.3%	4.1%	48.2%	100.0%	41.8%		
2006	**2005**	2,307	50	720	40	6,872	713	20,332	31,034	**119,755**		**409**
	%	7.4%	0.2%	2.3%	0.1%	22.1%	2.3%	65.5%	100.0%	44.4%		
2007	**2006**	7,333	45	458	24	7,430	322	56,010	71,622	**209,323**		**424**
	%	10.2%	0.1%	0.6%	0.0%	10.4%	0.4%	78.2%	100.0%	54.9%		

*** These totals must agree**

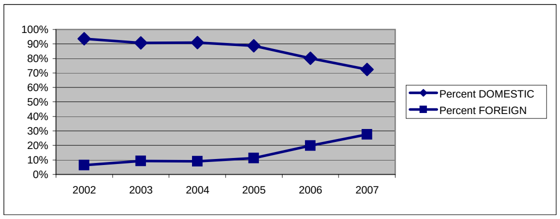
**** These totals must agree**

Table 7: Thirteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2007: Enrollment by Race and Ethnicity

7E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2007

		ENROLLMENT					PROTOCOLS				
FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC	Percent DOMESTIC	Total FOREIGN	Percent FOREIGN	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols	Percent Domestic Protocols	Number of FOREIGN Protocols	Percent Foreign Protocols
2002	2001	474,747	444,436	93.6%	30,311	6.4%	754	582	77.2%	172	22.8%
2003	2002	536,267	486,857	90.8%	49,410	9.2%	852	643	75.5%	209	24.5%
2004	2003	545,367	496,241	91.0%	49,126	9.0%	573	549	95.8%	24	4.2%
2005	2004	493,000	437,902	88.8%	55,098	11.2%	547	517	94.5%	30	5.5%
2006	2005	499,430	400,297	80.2%	99,133	19.8%	624	564	90.4%	60	9.6%
2007	2006	591,159	428,440	72.5%	162,719	27.5%	653	609	93.3%	44	6.7%

Percentage of Phase III Domestic and Foreign Enrollment



Number of Phase III Domestic and Foreign protocols

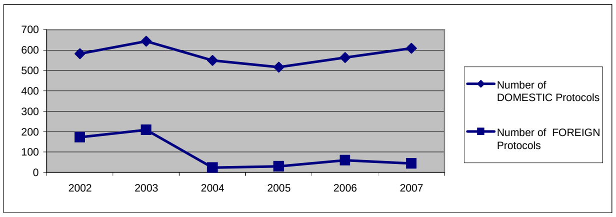


Table 7E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increased from FY 2002 - 2007.
2. The Domestic enrollment decreased to approximately 72.5%, while Foreign enrollment increased to approximately 27.5% in 2007.
3. The vast majority of protocols in FY 2004 - 2007 are domestic protocols.

7F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2007

FY Reported	FY Funded	FOREIGN Phase III Minority	FOREIGN Phase III Total	DOMESTIC Phase III Minority	DOMESTIC Phase III Total
2002	2001	18,308	30,311	92,961	444,436
		60.4%	100.0%	20.9%	100.0%
2003	2002	23,927	49,410	109,376	486,857
		48.4%	100.0%	22.5%	100.0%
2004	2003	37,126	49,126	125,813	496,241
		75.6%	100.0%	25.4%	100.0%
2005	2004	44,281	55,098	109,910	437,902
		80.4%	100.0%	25.1%	100.0%
2006	2005	84,412	99,133	83,034	400,297
		85.2%	100.0%	20.7%	100.0%
2007	2006	156,533	162,713	79,769	383,050
		96.2%	100.0%	20.8%	100.0%

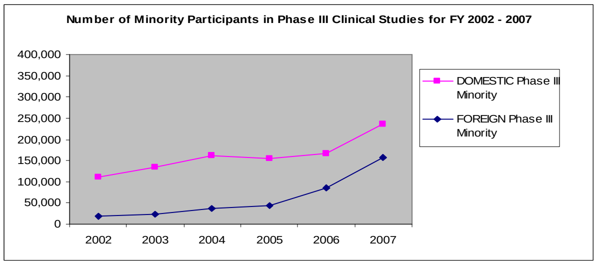


Table 7F Comments:

1. The Total Phase III Minority Foreign Participants increased from 60.4% in 2002 to 96.2% in 2007.
2. The Total Phase III Minority Domestic Participants varied from 20.7% to 25.4% between 2002 and 2007.

Table 8: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported: FY2002-2007: Enrollment Using U.S. Race/Ethnicity Categories

8A . FIVE YEAR SUMMARY TOTALS: DOMESTIC SUBJECTS IN DOMESTIC PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**6,583,087**	**3,506,787**	**59,995**	**10,149,869**	**2,754,820**	**8,425**
	%	64.9%	34.6%	0.6%	100.0%	27.1%	
2003	**2002**	**7,392,404**	**4,393,496**	**125,457**	**11,911,357**	**2,935,363**	**9,578**
	%	62.1%	36.9%	1.1%	100.0%	24.6%	
2004	**2003**	**8,881,299**	**5,199,765**	**278,729**	**14,359,793**	**3,464,356**	**9,760**
	%	61.8%	36.2%	1.9%	100.0%	24.1%	
2005	**2004**	**7,887,209**	**4,515,242**	**267,407**	**12,669,858**	**3,468,864**	**9,862**
		62.3%	35.6%	2.1%	100.0%	27.4%	
2006	**2005**	**7,684,453**	**3,566,577**	**174,671**	**11,425,701**	**3,301,135**	**10,294**
		67.3%	31.2%	1.5%	100.0%	28.9%	
2007	**2006**	**9,397,957**	**6,389,817**	**392,814**	**16,180,588**	**4,283,738**	**10,463**
		58.1%	39.5%	2.4%	100.0%	26.5%	

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Table 8A Comments

1. There were approximately an average of 62.4% females, 36.0% males and 1.7% of unknown sex enrolled in domestic
2. There were approximately an average of 26.3% domestic minority subjects enrolled in domestic protocols from 2002-2007.
3. Total domestic enrollment ranged from 10.1M to 16.2M during the past 6 years.
4. The number of domestic protocols increased from 8,425 to 10,463 in 6 years

NOTE on FY2002 Reported Data:

One domestic study had an enrollment of 540,833 subjects (Old Form).
One domestic study had an enrollment of 1,571,305 subjects (Old Form).

NOTE on FY2003 Reported Data:

One domestic study had an enrollment of 800,000 subjects (New Form).
One domestic study had an enrollment of 1,389,920 subjects (New Form).
One domestic study had an enrollment of 1,799,820 subjects (New Form).

NOTE on FY2004 Reported Data:

One domestic study had an enrollment of 540,833 subjects (New Form).
One domestic study had an enrollment of 800,000 subjects (New Form).
One domestic study had an enrollment of 1,138,302 subjects (New Form).
One domestic study had an enrollment of 1,419,475 subjects (New Form).
One domestic study had an enrollment of 1,799,820 subjects (New Form).

NOTE on FY2005 Reported Data:

One domestic study had an enrollment of 540,833 subjects (New Form).
One domestic study had an enrollment of 800,000 subjects (New Form).
One domestic study had an enrollment of 1,595,620 subjects (New Form).
One domestic study had an enrollment of 1,799,820 subjects (New Form).

NOTE on FY2006 Reported Data:

One domestic study had an enrollment of 875,010 subjects (New Form).
One domestic study had an enrollment of 1,964,668 subjects (New Form).
One domestic study had an enrollment of 540,833 subjects (New Form).

NOTE of FY2007 Reported Data:

One domestic study had an enrollment of 1,817,915 subjects (New Form).
One domestic study had an enrollment of 1,879,841 subjects (New Form).
One domestic study had an enrollment of 2,024,369 subjects (New Form).

Table 8: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2007: Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 8B, 8C and 8D are combined to provide the summary data in Table A.

8B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other		Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority Categories (shaded): OLD FORM		Number of Domestic Protocols with Enrollment data (Old Form):
2002	**2001**	45,639	752,203	673,726	378,300	3,880,431	316,053		6,046,352	1,849,868		**5,783**
	%	0.8%	12.4%	11.1%	6.3%	64.2%	5.2%		100.0%	30.6%		
2003	**2002**	36,238	249,420	455,329	264,336	3,100,815	266,339		4,372,477	1,005,323		**4,478**
	%	0.8%	5.7%	10.4%	6.0%	70.9%	6.1%		100.0%	23.0%		
2004	**2003**	28,953	196,647	322,078	194,762	2,273,619	157,464		3,173,523	742,440		**2,702**
	%	0.9%	6.2%	10.1%	6.1%	71.6%	5.0%		100.0%	23.4%		
2005	**2004**	22,375	89,119	210,465	126,351	1,245,337	93,239		1,786,886	448,310		**1,736**
	%	1.3%	5.0%	11.8%	7.1%	69.7%	5.2%		100.0%	25.1%		
2006	**2005**	19,628	51,701	148,224	74,312	866,683	61,480		1,222,028	293,865		**1,361**
	%	1.6%	4.2%	12.1%	6.1%	70.9%	5.0%		100.0%	24.0%		
2007	**2006**	5,372	51,740	238,003	81,677	1,095,702	48,625		1,521,119	376,792		**1,092**
	%	0.4%	3.4%	15.6%	5.4%	72.0%	3.2%		100.0%	24.8%		

8C. NEW FORM PART A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	**2001**	74,593	174,215	473,699	7,623	2,626,547	30,200	716,640	4,103,517	2,785,590	285,921	1,032,006	4,103,517
	%	1.8%	4.2%	11.5%	0.2%	64.0%	0.7%	17.5%	100.0%	67.9%	7.0%	25.1%	100.0%
2003	**2002**	61,526	295,061	897,518	23,068	5,161,965	94,138	1,005,604	7,538,880	6,003,326	602,018	933,536	7,538,880
	%	0.8%	3.9%	11.9%	0.3%	68.5%	1.2%	13.3%	100.0%	79.6%	8.0%	12.4%	100.0%
2004	**2003**	97,854	485,137	1,280,129	42,945	7,772,927	172,185	1,335,093	11,186,270	8,893,158	720,551	1,572,561	11,186,270
	%	0.9%	4.3%	11.4%	0.4%	69.5%	1.5%	11.9%	100.0%	79.5%	6.4%	14.1%	100.0%
2005	**2004**	291,044	655,959	1,232,957	42,993	7,485,193	164,096	1,010,730	10,882,972	9,120,293	721,138	1,041,541	10,882,972
	%	2.7%	6.0%	11.3%	0.4%	68.8%	1.5%	9.3%	100.0%	83.8%	6.6%	9.6%	100.0%
2006	**2005**	111,048	946,613	1,032,199	35,142	6,844,960	178,275	1,055,436	10,203,673	8,384,360	796,556	1,022,757	10,203,673
	%	1.1%	9.3%	10.1%	0.3%	67.1%	1.7%	10.3%	100.0%	82.2%	7.8%	10.0%	100.0%
2007	**2006**	129,830	892,410	1,719,631	46,569	10,028,992	270,005	1,572,032	14,659,469	11,991,388	1,002,302	1,665,779	14,659,469
	%	0.9%	6.1%	11.7%	0.3%	68.4%	1.8%	10.7%	100.0%	81.8%	6.8%	11.4%	100.0%

8D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	Domestic Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Domestic Protocols with Enrollment data (New
2002	**2001**	1,163	436	12,005	98	69,313	5,626	75,309	163,950	**904,952**		**2,642**
	%	0.7%	0.3%	7.3%	0.1%	42.3%	3.4%	45.9%	100.0%	22.1%		
2003	**2002**	3,756	1,950	13,345	678	349,844	23,560	208,885	602,018	**1,930,040**		**5,100**
	%	0.6%	0.3%	2.2%	0.1%	58.1%	3.9%	34.7%	100.0%	25.6%		
2004	**2003**	6,293	5,026	12,498	2,037	356,575	51,031	287,091	720,551	**2,721,916**		**7,058**
	%	0.9%	0.7%	1.7%	0.3%	49.5%	7.1%	39.8%	100.0%	24.3%		
2005	**2004**	22,057	7,810	19,282	1,981	362,707	36,503	270,798	721,138	**3,020,554**		**8,126**
	%	3.1%	1.1%	2.7%	0.3%	50.3%	5.1%	37.6%	100.0%	27.8%		
2006	**2005**	15,498	6,540	19,870	1,505	374,830	49,150	329,163	796,556	**3,007,270**		**8,933**
	%	1.9%	0.8%	2.5%	0.2%	47.1%	6.2%	41.3%	100.0%	29.5%		
2007	**2006**	20,932	6,875	28,078	3,199	493,196	94,717	355,305	1,002,302	**3,906,946**		**9,371**
	%	2.1%	0.7%	2.8%	0.3%	49.2%	9.4%	35.4%	100.0%	26.7%		

*** These totals must agree**
**** These totals must agree**

Table 9: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2007:Enrollment Using U.S. Race/Ethnicity Categories

9A . Phase III SIX YEAR SUMMARY TOTALS: DOMESTIC SUBJECTS IN DOMESTIC PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**264,517**	**179,179**	**740**	**444,436**	**92,961**	**582**
	%	59.5%	40.3%	0.2%	100.0%	20.9%	
2003	**2002**	**266,913**	**218,166**	**1,778**	**486,857**	**109,376**	**643**
	%	54.8%	44.8%	0.4%	100.0%	22.5%	
2004	**2003**	**277,333**	**217,890**	**1,018**	**496,241**	**125,813**	**549**
	%	55.9%	43.9%	0.2%	100.0%	25.4%	
2005	**2004**	**261,589**	**174,137**	**2,176**	**437,902**	**109,910**	**517**
	%	59.7%	39.8%	0.5%	100.0%	25.1%	
2006	**2005**	**258,467**	**137,621**	**4,209**	**400,297**	**83,034**	**564**
	%	64.6%	34.4%	1.1%	100.0%	20.7%	
2007	**2006**	**228,289**	**183,878**	**16,273**	**428,440**	**88,339**	**609**
	%	53.3%	42.9%	3.8%	100.0%	20.6%	

Table 9A Comments:

1. There were approximately an average of 57.8% females, 41.2% males and 1.0% of unknown sex enrolled in Phase III domestic protocols from 2002-2007.

2. There were approximately an average of 22.6% domestic minority subjects enrolled in domestic Phase III protocols from 2002-2007.
3. Total domestic Phase III enrollment ranged from 400,297 to 496,241 during these 6 years.
4. The number of domestic Phase III protocols ranged from 517 to 643 between Fiscal Years 2002 and 2007.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Table 9: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2007:Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 9B, 9C and 9D are combined to provide the summary data in Table A.

9B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other		Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority Categories (shaded): OLD FORM		Number of Domestic Protocols with Enrollment data (Old Form):
2002	**2001**	1,586	8,291	49,184	27,912	305,964	10,670		403,607	86,973		**494**
	%	0.4%	2.1%	12.2%	6.9%	75.8%	2.6%		100.0%	21.5%		
2003	**2002**	1,612	7,610	48,975	25,567	322,600	8,538		414,902	83,764		**468**
	%	0.4%	1.8%	11.8%	6.2%	77.8%	2.1%		100.0%	20.2%		
2004	**2003**	1,504	6,739	45,233	31,967	262,671	6,447		354,561	85,443		**286**
	%	0.4%	1.9%	12.8%	9.0%	74.1%	1.8%		100.0%	24.1%		
2005	**2004**	1,319	5,488	39,401	20,646	229,235	4,493		300,582	66,854		**205**
	%	0.4%	1.8%	13.1%	6.9%	76.3%	1.5%		100.0%	22.2%		
2006	**2005**	996	4,505	20,325	9,512	171,191	5,673		212,202	35,338		**207**
	%	0.5%	2.1%	9.6%	4.5%	80.7%	2.7%		100.0%	16.7%		
2007	**2006**	751	3,941	21,581	9,331	168,127	4,254		207,985	35,604		**204**
	%	0.4%	1.9%	10.4%	4.5%	80.8%	2.0%		100.0%	17.1%		

9C. NEW FORM Part A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	**FY Funded**	**American Indian or Alaska Native**	**Asian**	**Black or African American**	**Native Hawaiian or Pacific Islander**	**White**	**More Than One Race**	**Unknown or Not Reported**	***Total of All Subjects by Racial Categories (New Form)**	**Not Hispanic**	****Hispanic or Latino**	**Unknown/ Not Reported**	***Total of All Subjects by Ethnic Category**
2002	**2001**	159	798	3,199	52	34,541	560	1,520	40,829	34,662	1,629	4,538	40,829
	%	0.4%	2.0%	7.8%	0.1%	84.6%	1.4%	3.7%	100.0%	84.9%	4.0%	11.1%	100.0%
2003	**2002**	477	2,586	14,031	220	46,774	989	6,878	71,955	55,575	7,828	8,552	71,955
	%	0.7%	3.6%	19.5%	0.3%	65.0%	1.4%	9.6%	100.0%	77.2%	10.9%	11.9%	100.0%
2004	**2003**	1,396	4,373	22,307	611	106,260	1,849	4,884	141,680	123,770	10,863	7,047	141,680
	%	1.0%	3.1%	15.7%	0.4%	75.0%	1.3%	3.4%	100.0%	87.4%	7.7%	5.0%	100.0%
2005	**2004**	1,775	4,920	24,390	462	93,662	3,063	9,048	137,320	118,528	9,773	9,019	137,320
	%	1.3%	3.6%	17.8%	0.3%	68.2%	2.2%	6.6%	100.0%	86.3%	7.1%	6.6%	100.0%
2006	**2005**	2,724	5,312	23,267	530	118,577	4,077	33,608	188,095	141,688	13,550	32,857	188,095
	%	1.4%	2.8%	12.4%	0.3%	63.0%	2.2%	17.9%	100.0%	75.3%	7.2%	17.5%	100.0%
2007	**2006**	2,314	4,294	21,141	553	130,085	3,974	58,094	220,455	146,482	21,600	52,373	220,455
	%	1.0%	1.9%	9.6%	0.3%	59.0%	1.8%	26.4%	100.0%	66.4%	9.8%	23.8%	100.0%

9D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	Domestic Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Domestic Protocols with Enrollment data (New Form):
2002	**2001**	49	21	31	4	660	304	560	1,629	**5,988**		**88**
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	14.7%		
2003	**2002**	37	70	186	23	2,113	203	5,196	7,828	**25,612**		**175**
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	35.6%		
2004	**2003**	269	59	193	26	7,262	482	2,572	10,863	**40,370**		**263**
	%	2.5%	0.5%	1.8%	0.2%	66.9%	4.4%	23.7%	100.0%	28.5%		
2005	**2004**	371	42	446	45	3,663	423	4,783	9,773	**43,056**		**312**
	%	3.8%	0.4%	4.6%	0.5%	37.5%	4.3%	48.9%	100.0%	31.4%		
2006	**2005**	458	47	507	40	5,544	712	6,242	13,550	**47,696**		**357**
	%	3.4%	0.3%	3.7%	0.3%	40.9%	5.3%	46.1%	100.0%	25.4%		
2007	**2006**	300	44	454	24	7,360	319	13,099	21,600	**44,165**		**405**
	%	1.4%	0.2%	2.1%	0.1%	34.1%	1.5%	60.6%	100.0%	23.9%		

*** These totals must agree**

**** These totals must agree**

Table 10. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2007: Enrollment Using U.S. Race/Ethnicity Categories

10A . SIX YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**553,056**	**379,294**	**13,833**	**946,083**	**777,461**	**482**
	%	58.5%	40.1%	1.5%	100.0%	82.2%	
2003	**2002**	**1,122,077**	**1,728,000**	**10,820**	**2,860,897**	**2,452,329**	**638**
	%	39.2%	60.4%	0.4%	100.0%	85.7%	
2004	**2003**	**2,007,798**	**2,542,127**	**14,202**	**4,564,127**	**4,147,255**	**365**
	%	44.0%	55.7%	0.3%	100.0%	90.9%	
2005	**2004**	**1,616,713**	**1,426,665**	**9,516**	**3,052,894**	**2,776,565**	**371**
	%	53.0%	46.7%	0.3%	100.0%	90.9%	
2006	**2005**	**1,788,820**	**1,605,628**	**10,781**	**3,405,229**	**3,087,181**	**464**
	%	52.5%	47.2%	0.3%	100.0%	90.7%	
2007	**2006**	**754,633**	**497,976**	**15,261**	**1,267,870**	**932,686**	**451**
	%	59.5%	39.3%	1.2%	100.0%	73.6%	

Table 10AComments:

1. The percent females varied from 39.2% to 59.5% in foreign protocols from 2002-2007; the percent males varied from 39.3% to 60.4%.
2. The percent foreign subjects enrolled using OMB racial/ethnic categories in foreign protocols varied from 73.6% to 90.9% from 2002 to 2007.
3. Total foreign enrollment ranged from 946,083 to 4,564,127 during the past 6 years.
4. The number of foreign protocols ranged from 365 to 638 during the past 6 years

NOTE on FY2002 Reported Data:

One study in Vietnam had an enrollment of 302,381 subjects (Old Form).

NOTE on FY2003 Reported Data:

One study in Vietnam had an enrollment of 302,381 subjects (Old Form).
One study in China had an enrollment of 1,910,000 subjects (New Form).

NOTE on FY2004 Reported Data:

One study in China had an enrollment of 1,910,000 subjects (New Form).
One study in India had an enrollment of 2,000,000 subjects (New Form).

NOTE on FY2005 Reported Data:

One study in India had an enrollment of 2,200,000 subjects (New Form).

NOTE on FY2006 Reported Data:

One study in India had an enrollment of 2,200,000 subjects (New Form).

NOTE on FY2007 Reported Data:

No foreign studies reported an enrollment greater than 100,000 subjects.

Table 10. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2007: Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 10B, 10C and 10D are combined to provide the summary data in Table A.

10B.OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other		Total Foreign Enrollment (Old Form)	FOREIGN Subtotal Using US Minority Categories (shaded): OLD FORM		Number of Foreign Protocols with Enrollment data (Old Form):
2002	2001	69	468,958	21,407	19,075	143,768	3,565		656,842	509,509		380
	%	0.0%	71.4%	3.3%	2.9%	21.9%	0.5%		100.0%	77.6%		
2003	2002	341	481,122	17,097	24,187	137,469	12,562		672,778	522,747		425
	%	0.1%	71.5%	2.5%	3.6%	20.4%	1.9%		100.0%	77.7%		
2004	2003	434	110,405	20,110	19,560	74,910	14,666		240,085	150,509		80
	%	0.2%	46.0%	8.4%	8.1%	31.2%	6.1%		100.0%	62.7%		
2005	2004	0	165,479	19,150	8,621	21,752	9,166		224,168	193,250		50
	%	0.0%	73.8%	8.5%	3.8%	9.7%	4.1%		100.0%	86.2%		
2006	2005	20	80,085	724	4,284	16,358	1,751		103,222	85,113		30
	%	0.0%	77.6%	0.7%	4.2%	15.8%	1.7%		100.0%	82.5%		
2007	2006	0	2	1	1,515	1,685	5		3,208	1,518		6
	%	0.0%	0.1%	0.0%	47.2%	52.5%	0.2%		100.0%	47.3%		

10C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	3,271	180,022	68,071	14,013	19,970	741	3,153	289,241	278,618	6,064	4,559	289,241
	%	1.1%	62.2%	23.5%	4.8%	6.9%	0.3%	1.1%	100.0%	96.3%	2.1%	1.6%	100.0%
2003	2002	2,018	1,842,941	62,572	14,501	253,745	5,324	7,018	2,188,119	2,158,933	9,623	19,563	2,188,119
	%	0.1%	84.2%	2.9%	0.7%	11.6%	0.2%	0.3%	100.0%	98.7%	0.4%	0.9%	100.0%
2004	2003	193	3,860,259	99,728	11,507	292,142	14,056	46,157	4,324,042	4,275,684	35,788	12,570	4,324,042
	%	0.0%	89.3%	2.3%	0.3%	6.8%	0.3%	1.1%	100.0%	98.9%	0.8%	0.3%	100.0%
2005	2004	1,171	2,390,404	125,305	10,293	187,697	18,857	94,999	2,828,726	2,683,871	52,801	92,054	2,828,726
	%	0.0%	84.5%	4.4%	0.4%	6.6%	0.7%	3.4%	100.0%	94.9%	1.9%	3.3%	100.0%
2006	2005	30,519	2,516,589	219,140	3,318	244,057	143,279	145,105	3,302,007	2,923,885	257,756	120,366	3,302,007
	%	0.9%	76.2%	6.6%	0.1%	7.4%	4.3%	4.4%	100.0%	88.5%	7.8%	3.6%	100.0%
2007	2006	15,587	464,490	293,064	10,580	312,491	8,063	160,387	1,264,662	1,025,736	166,790	72,136	1,264,662
	%	1.2%	36.7%	23.2%	0.8%	24.7%	0.6%	12.7%	100.0%	81.1%	13.2%	5.7%	100.0%

10D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Foreign Protocols with Enrollment data (New Form):
2002	2001	1,461	0	4	0	1,659	683	175	3,982	**267,952**		102
	%	36.7%	0.0%	0.1%	0.0%	41.7%	17.2%	4.4%	100.0%	92.6%		
2003	2002	1,644	3	1,222	0	632	4,528	1,594	9,623	**1,929,582**		213
	%	17.1%	0.0%	12.7%	0.0%	6.6%	47.1%	16.6%	100.0%	88.2%		
2004	2003	115	14	12,778	0	4,537	11,878	6,466	35,788	**3,996,746**		285
	%	0.3%	0.0%	35.7%	0.0%	12.7%	33.2%	18.1%	100.0%	92.4%		
2005	2004	682	6	164	0	26,161	14,664	11,124	52,801	**2,583,315**		321
	%	1.3%	0.0%	0.3%	0.0%	49.5%	27.8%	21.1%	100.0%	91.3%		
2006	2005	29,576	101	1,842	688	42,665	136,326	46,558	257,756	**3,002,068**		434
	%	11.5%	0.0%	0.7%	0.3%	16.6%	52.9%	18.1%	100.0%	90.9%		
2007	2006	16,681	550	3,234	1,115	46,034	5,816	93,360	166,790	**931,178**		445
	%	10.0%	0.3%	1.9%	0.7%	27.6%	3.5%	56.0%	100.0%	73.6%		

*** These totals must agree**

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Table 11. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2007: Enrollment Using U.S. Race/Ethnicity Categories

11A. Part A. Phase III SIX YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**14,359**	**15,911**	**41**	**30,311**	**18,308**	**172**
	%	47.4%	52.5%	0.1%	100.0%	60.4%	
2003	**2002**	**28,037**	**21,237**	**136**	**49,410**	**23,927**	**209**
	%	56.7%	43.0%	0.3%	100.0%	48.4%	
2004	**2003**	**24,020**	**25,023**	**83**	**49,126**	**37,126**	**24**
	%	48.9%	50.9%	0.2%	100.0%	75.6%	
2005	**2004**	**29,388**	**23,163**	**2,547**	**55,098**	**44,281**	**30**
	%	53.3%	42.0%	4.6%	100.0%	80.4%	
2006	**2005**	**55,599**	**42,354**	**1,180**	**99,133**	**84,412**	**60**
	%	56.1%	42.7%	1.2%	100.0%	85.2%	
2007	**2006**	**96,405**	**65,755**	**559**	**162,719**	**156,593**	**44**
	%	59.2%	40.4%	0.3%	100.0%	96.2%	

Table 11A Comments:

1. The percent females varied from 47.4% to 59.2% in Phase III foreign protocols from 2002-2007; the percent males varied from 40.4% to 52.5%.

2. The percent foreign subjects enrolled by U.S. Minority Categories in Phase III foreign protocols increased from 60.4% to 96.2% from 2002 to 2007.

3. Total Phase III foreign enrollment increased from 30,311 to 162,719 during these 6 years.

4. The number of Phase III foreign protocols ranged from 24 to 209 between the years 2002 and 2007.

Table 11. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2007: Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 11B, 11C and 11D are combined to provide the summary data in Table A.

11B.OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other		Total Foreign Enrollment (Old Form)	FOREIGN Subtotal Using US Minority Categories (shaded): OLD FORM		Number of Foreign Protocols with Enrollment data (Old Form):
2002	**2001**	59	12,269	2,807	1,724	9,579	1,558		27,996	16,859		**166**
	%	0.2%	43.8%	10.0%	6.2%	34.2%	5.6%		100.0%	60.2%		
2003	**2002**	77	12,428	280	3,499	15,054	8,077		39,415	16,284		**188**
	%	0.2%	31.5%	0.7%	8.9%	38.2%	20.5%		100.0%	41.3%		
2004	**2003**	1	12,068	52	1,007	3,093	7,603		23,824	13,128		**10**
	%	0.0%	50.7%	0.2%	4.2%	13.0%	31.9%		100.0%	55.1%		
2005	**2004**	0	12,252	1	1,183	2,257	14		15,707	13,436		**5**
	%	0.0%	78.0%	0.0%	7.5%	14.4%	0.1%		100.0%	85.5%		
2006	**2005**	16	12,295	30	12	4,533	675		17,561	12,353		**8**
	%	0.1%	70.0%	0.2%	0.1%	25.8%	3.8%		100.0%	70.3%		
2007	**2006**	0	2	1	2	1,662	5		1,672	5		**1**
	%	0.0%	0.1%	0.1%	0.1%	99.4%	0.3%		100.0%	0.3%		

11C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	**2001**	0	1	1,448	0	113	0	753	2,315	1,562	0	753	2,315
	%	0.0%	0.0%	62.5%	0.0%	4.9%	0.0%	32.5%	100.0%		0.0%	32.5%	32.5%
2003	**2002**	7	23	7,610	0	1,095	0	1,260	9,995	8,720	3	1,272	9,995
	%	0.1%	0.2%	76.1%	0.0%	11.0%	0.0%	12.6%	100.0%	87.2%	0.0%	12.7%	100.0%
2004	**2003**	0	12	21,414	0	553	2,570	753	25,302	21,972	2,572	758	25,302
	%	0.0%	0.0%	84.6%	0.0%	2.2%	10.2%	3.0%	100.0%	86.8%	10.2%	3.0%	100.0%
2005	**2004**	389	4,272	25,948	0	7,576	0	1,206	39,391	38,122	624	645	39,391
	%	1.0%	10.8%	65.9%	0.0%	19.2%	0.0%	3.1%	100.0%	96.8%	1.6%	1.6%	100.0%
2006	**2005**	1,906	27,048	27,513	5	8,093	169	26,838	91,572	60,670	17,484	3,418	81,572
	%	2.1%	29.5%	30.0%	0.0%	8.8%	0.2%	29.3%	100.0%	74.4%	21.4%	4.2%	100.0%
2007	**2006**	7,037	43,070	63,327	2	2,917	171	44,523	161,047	108,210	50,022	2,815	161,047
	%	4.4%	26.7%	39.3%	0.0%	1.8%	0.1%	27.6%	100.0%	67.2%	31.1%	1.7%	100.0%

11D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Foreign Protocols with Enrollment data (New Form):
2002	**2001**	0	0	0	0	0	0	0	0	**1,449**		**6**
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	62.6%		
2003	**2002**	0	0	0	0	2	0	1	3	**7,643**		**21**
	%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	33.3%	100.0%	76.5%		
2004	**2003**	0	0	0	0	2	2,570	0	2,572	**23,998**		**14**
	%	0.0%	0.0%	0.0%	0.0%	0.1%	99.9%	0.0%	100.0%	94.8%		
2005	**2004**	388	0	0	0	4	0	232	624	**30,845**		**25**
	%	62.2%	0.0%	0.0%	0.0%	0.6%	0.0%	37.2%	100.0%	78.3%		
2006	**2005**	1,849	3	213	0	1,328	1	14,090	17,484	**72,059**		**52**
	%	10.6%	0.0%	1.2%	0.0%	7.6%	0.0%	80.6%	100.0%	78.7%		
2007	**2006**	7,033	1	4	0	70	3	42,911	50,022	**156,588**		**43**
	%	14.1%	0.0%	0.0%	0.0%	0.1%	0.0%	85.8%	100.0%	97.2%		

*** These totals must agree**

**** These totals must agree**

APPENDICES

Appendix A

Historical Narrative on the Implementation of the NIH Inclusion Policy

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

Historical Background

The establishment and implementation of policies for the inclusion of women and minorities in clinical research funded by the National Institutes of Health (NIH) has its origins in the women's health movement. Following the issuance of the report of the Public Health Service Task Force on Women's Health in 1985, the NIH established a policy in 1986 for the inclusion of women in clinical research. This policy, which ***urged*** the inclusion of women, was first published in the NIH Guide to Grants and Contracts in 1987. Later that year, minority and other scientists at the NIH recognized the need to address the inclusion of minority populations. Therefore, in a later 1987 version of the NIH guide, a policy ***encouraging*** the inclusion of minorities in clinical studies was first published.

In July 1989, an *NIH Memorandum on Inclusion* stated that research solicitations should encourage inclusion of women and minorities and require a rationale if excluded, and that executive secretaries of scientific review groups should ensure that responsiveness to policy would be addressed and indicated in summary statements. In 1990, the *Congressional Caucus for Women's Issues* requested the U.S. General Accounting Office (GAO) to conduct an investigation into the implementation of the guidelines for the inclusion of women by NIH. This report, in Congressional testimony, indicated that the implementation of the policy for the inclusion of women was slow, not well communicated, that gender analysis was not implemented, and that the impact of this policy could not be determined. The GAO testimony also indicated that there were differences in the implementation of the policy recommending the inclusion of minorities, and that not all Institutes and Centers (ICs) factored adherence to these policies into the scientific merit review.

In order to ensure that the policies for inclusion were firmly implemented by NIH, the Congress made what had previously been policy into Public Law, through a section in the NIH Revitalization Act of 1993 (PL 103-43)[1], entitled *Women and Minorities as Subjects in Clinical Research*. In 1994, the NIH revised its inclusion policy to meet this mandate that women and minorities must be included in all of its clinical research studies. The Revitalization Act essentially reinforced the existing NIH policies, but with four major differences:

- that NIH ensure that women and minorities and their subpopulations be included in all clinical research;
- that women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to allow for valid analyses of differences in intervention effect;
- that cost is not allowed as an acceptable reason for excluding these groups; and,
- that NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies

Revised inclusion guidelines developed in response to this law were published in the *Federal Register*[2] in March 1994, and they became effective in September 1994. The result was that NIH could not and would not fund any grant, cooperative agreement or contract or support any intramural project to be conducted or funded in Fiscal Year 1995 and thereafter which did not comply with this policy. NIH administrative procedures allow consideration of applications through a peer-review system. During initial peer review, the Scientific Review Group (SRG) evaluates the proposed enrollment of each project involving human subjects and determines whether the plan to include women and minority subjects is scientifically acceptable. The implementation plan determines that an application may be unacceptable if it: 1) fails to provide sufficient information about target enrollment; 2) does not adequately justify limited or lack of inclusion of women or minorities; or 3) does not realistically address recruitment and retention. For NIH-defined Phase III clinical trials, the Scientific Review Group (SRG) also evaluates the description of plans to conduct analyses, as appropriate, to address differences in the intervention effect by sex/gender and/or racial/ethnic groups. Applications with unacceptable inclusion plans receive an unacceptable gender or minority code, resulting in a bar-to-funding. Such clinical research studies cannot be funded until NIH staff is assured of compliance from the investigators. This may involve changes related to study design. Sometimes applicants are able to remedy the deficiencies found during initial review by providing additional information about the intended enrollment demographics. Research awards covered by this policy require the grantee to report annually on enrollment of women and men, and on the race and ethnicity of research participants so that accrual can be monitored. Annual progress reports submitted by the grantee contain information on research progress which includes research participant enrollment, retention, and when available, preliminary and/or final analyses including analyses by sex/gender and race/ethnicity.

Strategies to ensure uniform implementation of the revised guidelines across the NIH were developed through the establishment and deliberations of an NIH Tracking and Inclusion Committee made up of representatives of the directors of each of the ICs. This trans-NIH committee, convened by the Office of Research on Women's Health (ORWH) and co-chaired with a senior IC official, meets on a regular basis, focusing on consistent and widespread adherence to the NIH guidelines by all the ICs. Working in collaboration with the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and other components of the NIH, the ORWH coordinates the activity of developing and establishing data collection and reporting methodologies to ensure uniform standards and definitions in the reporting of data on women and minority participants in NIH-funded clinical research.

To ensure NIH-wide adherence to the revised inclusion guidelines, in 1994 NIH conducted extensive training on the revised inclusion guidelines for more than 1,000 NIH staff members with review, program, grants management, and/or contract management responsibilities. Additionally, four publications were distributed to further reinforce adherence to the revised inclusion guidelines.(5-8) NIH staff, in turn, clarified the requirements to applicants, reviewers, and other members of the research community. NIH staff members, reviewers, and applicants received written guidance about the requirements that outlined, in great detail, the circumstances under which it may be acceptable to use study populations deficient in women or minority participants, pointing out that the justification must be compelling and the scientific objectives of the research must be maintained. Training was especially important in light of 1990 GAO findings that an earlier policy was inconsistently applied and had not been well communicated or understood within the NIH or in the research community.

A variety of outreach activities were initiated to explain the revised policy to the scientific research community and to clear up common misunderstandings about the new requirements. Recognizing the importance of both recruitment and retention of human subject volunteers, NIH issued several articles(9-10) and an outreach notebook, entitled *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research* (http://orwh.od.nih.gov/inclusion/outreach.pdf), that outlines elements of outreach processes, offers practical suggestions, and provides references to additional sources of information. The outreach notebook is available on the Office of Research on Women's Health Website http://orwh.od.nih.gov. It also includes the full text of the 1994 implementation guidelines as well as a questions and answers document to provide more detailed policy guidance and some of the more commonly asked questions. The ORWH also has available a full report of its workshop on "Recruitment and Retention of Women in Clinical Studies."

In June 1994, the ORWH convened a meeting of Institutional Review Board (IRB) chairs to discuss their role in implementing the revised policy. In 1996, ORWH reconvened these IRB chairs, along with representative members of the ORWH Recruitment and Retention Task Force, other experts, and representatives from NIH ICs, to discuss their experiences in implementing the 1994 guidelines. In these meetings, investigators expressed a number of lingering concerns, most notably whether it was realistic for the law to declare that cost is not a factor in designing clinical studies. Participants also raised questions about inclusion of women of childbearing potential, liability in clinical trials, and barriers to the recruitment of minority subjects. Other participants, however, noted that their worst fears about the 1994 guidelines did not materialize, in part because NIH focused on scientific considerations when developing its policy. They reported improved collaboration among institutions and emphasized the continued need for better outreach and for sharing information about effective recruitment strategies. Many noted the importance of considering community concerns, particularly those of minority populations who may feel that they are not included in enough research studies or who do not receive research results after participating in studies.

Continuing Implementation and Monitoring Activities: 2000 to the Present

Following a Congressional request for an assessment of NIH's progress in implementing the1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled *Women's Health - NIH Has Increased Its Efforts to Include Women in Research.*[3] It concluded that in the past decade, NIH has made significant progress in implementing a strengthened policy on including women in clinical research and highlighted several examples:

- NIH issued guidelines to implement the 1993 NIH Revitalization Act and conducted extensive training for scientists and reviewers;

- the review process for extramural research treats the inclusion of women and minorities as a matter of scientific merit, affecting a proposal's eligibility for funding;

- the intramural research program now implements the inclusion policy;

- NIH maintains a centralized inclusion tracking data system which serves as a tool for monitoring the implementation of the inclusion policy; and

- in fiscal year 1997, more that 62% of participants in NIH-funded clinical research studies were women; minority women were also well represented, however, the proportion of Hispanic women enrolled was below their proportion in the general population.

The GAO report also included two specific recommendations to the Director of NIH to ensure the following:

- that the requirement be implemented that Phase III clinical trials be designed and carried out to allow for the valid analysis of differences between women and men and communicate this requirement to applicants as well as requiring peer review groups to determine whether each proposed Phase III clinical trial is required to have such a study design, and that summary statements document the decision of the initial reviewers; and

- that the NIH staff who transmit data to the inclusion tracking data system receive ongoing training on the requirements and purpose of the system.

Immediately following the release of this report, an *NIH Subcommittee Reviewing Inclusion Issues* was formed, consisting of representatives from several ICs, ORWH, OER, and OIR, to reexamine NIH's system for tracking data on the inclusion of women and minorities in clinical research, recommend any necessary changes to improve its accuracy and performance, and reiterate the NIH policy. Several actions resulted to clarify the requirement for NIH-defined Phase III clinical trials to include women and minority groups, if scientifically appropriate, and for analysis of sex/gender and/or racial/ethnic differences to be planned and conducted by investigators engaged in NIH-funded research. These included:

- In October 2001, the **NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research and Amended Notice to the Guide for Grants and Contracts were updated and posted on the Internet with links to the ORWH home page and NIH web page,** *Inclusion of Women and Minorities Policy Implementation* at: http://grants.nih.gov/grants/funding/women_min/women_min.htm. These documents supercede the 1994 Federal Register notice (http://grants.nih.gov/grants/guide/notice-files/not94-100.html) **and the August 2000 notice in the NIH Guide to Grants and Contracts (**http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html**)**. These updated versions incorporate the definition of clinical research as reported in the 1997 Report of the NIH Director's Panel on Clinical Research and the Office of Management and Budget (OMB) Directive 15 racial and ethnic categories to be used when reporting population data. They also provide additional guidance on reporting analyses of sex/gender and racial/ethnic differences in intervention effects for NIH-defined Phase III clinical trials (See Appendix E).

    - The 1997 Report of the NIH Director's Panel on Clinical Research defined clinical research as: **(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research http://www.nih.gov/news/crp/97report/execsum.htm**

    - The 1997 Office of Management and Budget (OMB) Directive 15 minimum standards for maintaining, collecting and reporting data on race and ethnicity were incorporated into the updated Guide Notice for Grants and Contracts. The primary differences from the previous categories were: (1) the Hispanic population are considered an ethnicity and reported separately from racial data; (2) there is a separate racial category for Asian population data and Hawaiian and Pacific Islander population data; and 3) respondents are given the option of selecting more than one race. **http://www.whitehouse.gov/omb/fedreg/ombdir15.html** (See Appendix E)

    - An NIH Guide Notice was posted on the Internet with a link to the web page, *Inclusion of Women and Minorities Policy Implementation* at: http://grants.nih.gov/grants/funding/women_min/women_min.htm. This restated that NIH-defined Phase III clinical trials must be designed and conducted in a manner sufficient to allow for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other subjects.

- A new term and condition of award statement was developed and applied to awards made after October 1, 2000 that have NIH-defined Phase III clinical trials. This statement indicates that a description of plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups must be included in clinical trial protocols and the results of subset analyses must be reported to NIH in Progress Reports, Competitive Renewal Applications (or Contract Renewals/Extensions) and in the required Final Progress Report.

- Effective October 1, 2000, language was incorporated in the NIH solicitations for grant applications and contract proposals [Program Announcements (PAs), Request for Applications (RFAs), and Request for Proposals (RFPs)] that stated the requirements for NIH-defined Phase III clinical trials clarifying the requirements that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable, and b) all investigators must report accrual, and conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

- In April 2001, guidelines and instructions for reviewers and Scientific Review Administrators (SRAs) were developed to emphasize and clarify the need to review research proposals that are classified as NIH-defined Phase III clinical trials for both inclusion requirements and issues related to analyses by sex/gender and/or race/ethnicity. Instructions were developed for the proper documentation to include in summary statements to address adherence to these policies.

- Following completion of the updated guidelines and instructions, training to ensure compliance with this policy was provided to NIH program and review officials, grants and contracts management staff, and current and prospective research investigators. Several training initiatives were implemented:

    - As part of an NIH Symposium: Human Subjects Update, the revised policy on inclusion of women and minorities and the revised NIH Instructions to Reviewers Guidelines for Evaluating the Inclusion of Women and Minorities as Subjects in Clinical Research were used as the basis for a required training session for NIH staff. The revised training materials are permanently archived in the training materials for NIH staff on the NIH OER Intranet.

    - An additional training session regarding a Grants Policy Update: Humans and Animals was held in December, 2000 where several hundred additional extramural and intramural researchers were trained. Additional training materials for NIH staff that addresses the inclusion of human subjects can be found on the NIH OER Intranet.

    - Additional training sessions were held for all NIH program and grants management staff

- The PHS 398 Grant Application was significantly revised to provide additional instructions about the Women and Minorities Inclusion Policy and the revised form became mandatory as of May 10, 2005. These PHS 398 instructions about the Women and Minorities Inclusion Policy have also been included in the new federal application form SF-424 for NIH grants using the federal Grants.gov system (see http://era.nih.gov/ElectronicReceipt/). The application instructions included two significant changes in definitions. First, the NIH required use of a revised definition of clinical research (see below) that was reported in the 1997 Report of the NIH Director's Panel on Clinical research and adopted by NIH. Secondly, the Office of Management and Budget (OMB) Directive 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting", revised the definitions for the racial and ethnic categories to be used when reporting population data (see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html). In addition, NIH policy reemphasized that that NIH-defined Phase III clinical trials must be designed and conducted in a manner to allow for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other subjects.

- A videocast training session was held on "Sex/Gender and Minority Inclusion in Clinical Research." This session was developed for all program, grants management, review and contract staff who administer clinical research and provided information on the updated policies and procedures on sex/gender and minority inclusion. A comprehensive training manual explaining the new policies and procedures was developed as a training resource. The training session and manual is electronically available for all NIH staff.

- Reviewers are instructed on the policy through instructions provided with review materials as well as by orientation from the Scientific Review Administrator at the beginning of each SRG meeting. Additionally, a training session, "Inclusion of Children, Women, and Minorities: What SRA's and Reviewers Need to Know!" was held for the Center for Scientific Review and highlighted the requirements and issues for scientific review staff.

- The Clinical Center now has available a web-based educational module for the comprehensive training programs for intramural and other research investigators. All principal investigators are required to complete the *Clinical Research Training Course for Intramural Investigators* or equivalent prior to implementing a protocol and consideration is being given to making this a requirement for all investigators.

  The NIH has a public web-based educational module also available any investigators and key personnel involved in clinical research, whether in the extramural research community or at NIH entitled "Human Participant Protections Education for Research Teams" at http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp.This training course is one way for investigators to meet the requirement for human subjects education for all key personnel involved in NIH funded human subjects research.

- In 2003, the ORWH sponsored a workshop entitled, "Science Meets Reality: Recruitment and Retention of Women in Clinical Studies, and the Critical Role of Relevance." This workshop discussed lessons learned, continuing challenges and emerging ethical and policy issues concerning the recruitment and retention of women and other participants in clinical studies over the past decade. A copy of the report from the workshop is available on the ORWH website at http://orwh.od.nih.gov/pubs/SMR_Final.pdf.

The Office of Extramural Research (OER) has made available existing training materials on the Population tracking system website on the NIH Intranet. Information include: the training workbook, "Sex/Gender and Minority Inclusion in Clinical Research", a series of quick tips and case examples as well as the Help section of the Population Tracking module itself. Both OER and IC staff have provided training sessions at ICs, and the improvements have been presented to the main NIH functional groups representing program, review, policy, grants, budget and administrative support staff, as well as the NIH-wide Tracking and Inclusion Committee and the eRA Population Trackng User Group. The availability of training documents on the eRA Population Tracking User Group website has been widely distributed to NIH extramural staff. A training subcommittee of the full NIH Tracking and Inclusion committee has been established to develop new training documents and methods of training for NIH staff and the extramural research community during FY2007.

Major changes have been made to the Population tracking system to help NIH staff in monitoring compliance with the NIH Inclusion policy. For example, the Population Tracking Grant Snapshot report was revised to provide easy access for NIH staff to the population data. Additionally, several Population Inclusion reports were added to the NIH Query View Report (QVR) system, thus providing broader access to the data. As well, user roles were revised and expanded to all the Division of Extramural

Activities Support (DEAS) staff to assist in the data entry functions. The NIH Population Tracking Module for NIH staff was converted into a web-based application for easier access by NIH staff, with extensive participation and testing by module users, and the number of users has increased.

Communication and Outreach Efforts to the Scientific Community

In addition to training NIH staff on the updated guidelines for monitoring the inclusion of women and minorities in clinical research and the purpose of the new tracking system, NIH staff is providing outreach to the scientific community to help increase understanding of the revised inclusion policy and OMB requirements. These include:

- The slide show, "Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know!" was made available to Institute and Center staff to assist them in working with the extramural community. This information was also presented at regional meetings attended by extramural scientists and administrators, faculty and students.

- The *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research* was published in the fall of 2002 and is available to the research community and NIH staff. This publication discusses the elements of recruitment and retention, the NIH inclusion policy, 1997 OMB requirements for reporting race and ethnicity data, as well as information for application submission, peer review, and funding. The publication is posted on the ORWH website http://orwh.od.nih.gov as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm .

- In addition, the *Frequently Asked Questions (FAQs) for the Inclusion, Recruitment and Retention of Women and Minority Subjects in Clinical Research* complements the *Outreach Notebook* and provides additional guidance to researchers and NIH staff in a user friendly format. The *FAQs* is posted on the ORWH website http://orwh.od.nih.gov as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm.

These training and outreach efforts are designed to improve understanding of the sex/gender and minority inclusion policy and assist investigators and NIH staff to appropriately address these issues throughout the research grant and contract process. Investigators are instructed to address women and minority inclusion issues in the development of their applications and proposals for clinical research.

Monitoring Compliance: Extramural and Intramural Population Data Analysis

When assessing inclusion data, enrollment figures should not be directly compared to the national census figures. The goal of the NIH policy is not to satisfy any quotas for proportional representation, but rather to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will be generalizable to the entire population of the United States. The numbers of women or minority subgroups included in a particular study depends upon the scientific question addressed in the study and the prevalence among women and minority subpopulations of the disease, disorder, or condition under investigation. Scientific Review Groups are instructed to focus on scientific considerations when assessing the planned enrollment for a particular study.

NIH has monitored aggregate demographic data for study populations through the evolving NIH computerized tracking system since fiscal year 1994, and tracking the inclusion of women and minorities in clinical studies is well established in all ICs. Members of the NIH Tracking and Inclusion Committee continue to work on ways to refine and improve data collection methods and the quality of the data entered by each IC into this system. In May 2002, the NIH deployed a new population tracking system for monitoring the inclusion of women and minorities in clinical research. This system provides easier data entry and project monitoring for NIH staff, creates clear and timely NIH reports on inclusion data, and incorporates the 1997 OMB Office of Management and Budget (OMB) standards for the classification of federal data on race and ethnicity. Following the implementation of the population tracking module, an *eRA Population Tracking User Group* consisting of representatives from several ICs, was formed to evaluate the system, recommend improvements and modifications, and provide continuous feedback related to system use. The re-engineered population tracking system continues to be refined based on input from the NIH user community.

- NIH has published an on-line user's guide and began offering 2-hour Population Tracking System demonstrations as well as in-depth, hands-on training sessions on the use of the population tracking system. The availability of training documents on the eRA Population Tracking User Group website has been widely distributed to NIH extramural staff.

The aggregate data enable the NIH to measure inclusion in order to formulate more specific questions about gaps in enrollment and to design studies to respond to those questions. Data compiled in future years allows for longitudinal examination of trends and continued monitoring of compliance, although this will be more difficult for minority trends because of a change in how these data are collected (see next section).

A review of intramural inclusion data indicates that the intramural research program continues to be compliant with the reporting requirements adhered to by the extramural community and outlined in the NIH Implementation Guidelines on the Inclusion of Women and Minority Subjects in Research Studies. The Clinical Center Medical Executive Committee (MEC) has taken a leading role in assuring that investigators conducting clinical research protocols in the Clinical Center are trained and competent in the conduct of clinical research. To this end, the MEC designed and endorsed the Standards for Clinical Research within the NIH Intramural Research Program. This set of standards, endorsed by the Clinical Center's Board of Governors and the NIH Institute Directors, sets forth guidelines for the infrastructure, training, education, and monitoring required for safe and effective conduct of clinical research.

Format Changes for Reporting Race and Ethnicity Data Beginning in FY 2002

The 1997 Office of Management and Budget (OMB) Directive 15 minimum standards for maintaining, collecting and reporting data on race and ethnicity directs changes in how data are reported to NIH. The FY 2003 and FY 2004 tables describe data using both the 1977 and 1997 OMB standards for reporting data on race and ethnicity. Implementation of the 1997 OMB standards involved a number of changes including collecting and reporting information on race and ethnicity separately (Hispanic/Latinos are considered an ethnicity and reported separately from racial data); using the new definitions and categories for ethnicity and race (a separate racial category for Asian population data and Hawaiian/Pacific Islander data); and allowing respondents the option of selection more than one race or only one race.

The 1997 OMB reporting format does not allow direct comparison of ethnic and racial data with similar data collected under the 1977 OMB standards because the categories and methods for collecting the data are fundamentally different. Changes in the standardization of definitions and business rules across the NIH for improving the data entered in the population tracking system are reflected in data reported beginning in FY2002. This transition period makes comparisons with prior FY 2002 data difficult. However, implementation of these changes will improve the consistency and comparability for future reporting.

Conclusion and Current Status

NIH staff continue to monitor, document, and work with grantees and contractors to ensure compliance with the inclusion policy. Program Officials provide technical assistance to investigators as they develop their applications and proposal throughout the application process. Review Officials introduce and discuss with reviewers the Guidelines/Instructions for reviewing the Inclusion of Women and Minorities in Clinical Research as well as the instructions and requirements for designing Phase III Clinical Trials in order that valid analyses can be conducted for sex/gender and ethnic/racial differences. At the time of award and submission of progress reports, program officials monitor and verify that inclusion policy requirements are met. When new and competing continuation applications that are selected for payment are deficient in meeting policy requirements, grants management staff and program officials will withhold funding until the principal investigator has satisfactorily addressed the policy requirements.

References

1. Public Law 103-43. National Institutes of Health Revitalization Act of 1993. 42 USC 289 (a)(1).
2. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508-14513 (1994).
3. *Women's Health: NIH Has Increased Its Efforts to Include Women in Research* (GAO/HEHS-00-96, May, 2000).
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5. Hayunga, E.G., Costello, M.D. Pinn, V.W., Demographics of Study Populations, *Applied Clinical Trials*, Vol. 6, No.1, p. 41-45, 1997.
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9. McCarthy, C.R., Historical Background of Clinical Trials Involving Women and Minorities, *Academic Medicine*, Vol. 69, No.9, p. 695-698, 1994.
10. Pinn, V.W., The Role of the NIH's Office of Research on Women's Health, *Academic Medicine,* Vol. 69, No. 9, p. 698-702, 1994.
11. Gallin, J, (2002). Principles and Practices of Clinical Research: Chapter 11 NIH Policy on the Inclusion of Women and Minorities as Subjects of Clinical Research, Academic Press, San Diego, California, pp 146-157.

For Additional Information on the implementation of the inclusion policy, please visit:

NIH Office of Extramural Research Inclusion of Women and Minorities Policy Implementation Website: http://grants.nih.gov/grants/funding/women_min/women_min.htm

Revitalization Act of 1993, 42 USC 289 (a)(1): http://grants.nih.gov/grants/guide/notice-files/not94-100.html

NIH Policy on Reporting Racial and Ethnicity Data: Subjects in Clinical Research, NIH Guide for Grants and Contracts Web page: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html

Office of Research on Women's Health Website: http://orwh.od.nih.gov/inclusion/inclreports.html

Appendix B

Explanation of Sex and Minority Codes

G1A	Includes both genders, scientifically acceptable.
G2A	Includes only women, scientifically acceptable.
G3A	Includes only men, scientifically acceptable.
G4A	Gender representation unknown, scientifically acceptable.
G1U	Includes both genders, but scientifically unacceptable.
G2U	Includes only women, scientifically unacceptable.
G3U	Includes only men, scientifically unacceptable.
G4U	Gender representation unknown, scientifically unacceptable.

M1A	Includes minorities and non-minorities, scientifically acceptable.
M2A	Includes only minorities, scientifically acceptable.
M3A	Includes only non-minorities, scientifically acceptable.
M4A	Minority representation unknown, scientifically acceptable.
M1U	Includes minorities and non-minorities, but scientifically unacceptable.
M2U	Includes only minorities, scientifically unacceptable.
M3U	Includes only non-minorities, scientifically unacceptable.
M4U	Minority representation unknown, scientifically unacceptable.

When an application receives a “U” (unacceptable) code it automatically receives a bar-to-funding as well. If the bar is removed, the “U” is converted to “R” to designate that change in status.

Appendix C

NIH Tracking and Inclusion Committee Members

- Full Committee

NIH Tracking and Inclusion Committee
2006 List of Members

Office of the Director

Office of Research on Women's Health
Vivian Pinn (Co-Chair), Angela Bates
Office of Extramural Research
Izja Lederhendler*, Katrina Pearson, Svetlana Diggs, Maria Koshy
Office of Acquisition, Management and Procurement
Rosemary Hamill*

National Cancer Institute
Gail Blaufarb*, Kim Witherspoon, Clarissa Douglass

National Eye Institute
Donald Everett*, William Darby

National Heart, Lung, and Blood Institute
Carl Roth (Co-Chair)*, Sharry Palagi, Barbara Marzetta

National Human Genome Research Institute
Bettie Graham*, Pam Sellman, Joy Boyer

National Institute on Aging
Robin Barr *, Karen Bashir, Nina Silverberg, Marilyn Miller

National Institute on Alcohol Abuse and Alcoholism
Van Van*, Patricia Powell

National Institute of Allergy and Infectious Diseases
Diane Adger-Johnson*, Susan Schafer, Diane Yerg, Martin Gutierrez

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Shahnaz Khan*, Frank Cromwell

National Institute of Child Health and Human Development
Eugene Hayunga*, Sandi Delcore

* Indicates the IC Lead Representative to the Tracking and Inclusion Committee

List of Members, continued...

National Institute on Deafness and Other Communication Disorders
Castilla McNamara*, Lana Shekim

National Institute of Dental and Craniofacial Research
Trenita Davis*

National Institute of Diabetes, Digestive and Kidney Disorders
Karl Malik*, Lauren Meskill, Garman Williams, Michelle Johnson, Karen Salomon

National Institute on Drug Addiction
Christie Espinosa*, Quandra Scudder

National Institute of Environmental Health Sciences
Martha Barnes*

National Institute of General Medical Sciences
Lori Burge*, Alison Cole

National Institute of Mental Health
Kathleen O'Leary *, Dawn Corbett, Sue Kennel

National Institute of Neurological Disorders and Stroke
Lynn Morin*, Kristy Woolbert, Aricia Ajose

National Institute of Nursing Research
Paul Cotton *, Angela Marshall

National Library of Medicine
Hua-Chuan Sim*, Valerie Florence

Warren G. Magnuson Clinical Center
Kim Jarema*

National Center for Complementary and Alternative Medicine
April Bower*

* Indicates the IC Lead Representative to the Tracking and Inclusion Committee

List of Members, continued...

National Center for Research Resources
Sheila McClure*, Delores Lee, Patricia Newman, Stephen Seidel, Louise Ramm

Fogarty International Center
Aron Primack*, Shena Wilson

Center for Scientific Review
Joy Gibson*

National Center for Minority Health and Health Disparaties
Derrick Tabor*, Nathaniel Stinson, Francisco Sy

National Institute of Biomedical Imaging and Bioengineering
Valery Gordon*, Anthony Dempsey

* Indicates the IC Lead Representative to the Tracking and Inclusion Committee

Appendix D

Internet Homepage:

Inclusion of Women and Minorities Policy Implementation

http://grants.nih.gov/grants/funding/women_min/women_min.htm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
Office of Extramural Research

Inclusion of Women and Minorities As Participants In Research Involving Human Subjects - Policy Implementation Page

Current Policy Documents and References:

- Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know! (11/21/2002) - A PowerPoint slide show highlighting the rationale and major components of the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research, as well as the 1997 OMB standards for collecting and presenting data on ethnicity and race.

- Annual Comprehensive Reports on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research - Reports beginning with Fiscal Year 1997 data from the ORWH Inclusion of Women in Clinical Research Page.

- 10/09/2001 NIH Guide Notice - The NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research was amended October 2001. **Click here for a complete copy of the Amended Policy** that provides full explanation of the October 2001 policy notice.

- Inclusion Table (PDF or RTF) - (07/25/2001) - Prior format for reporting sex/gender and race/ethnicity data using the 1977 OMB standards for the classification of federal data on race and ethnicity. This format is superceded by the Target/Planned Enrollment Table and Inclusion Enrollment Reports that use the 1997 OBM standards for the classification of federal data on race and ethnicity.

- What Form Should PIs Use for Population Tracking? (New versus OLD) - (PDF or MS Word) - (08/2003) - Information on when to use 05/01 Population Tracking form versus the previous 04/98 version.

- 08/08/2001 NIH Guide Notice - NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research. This notice provides additional guidance and instruction for using the revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity found in the PHS 398 (rev. 9/04) and PHS 2590 (rev. 9/04) instructions and forms.

- Outreach Notebook and Outreach Frequently Asked Questions - are available to help investigators to understand and comply with the NIH's inclusion policies. ORWH collaborated in the preparation and publication of these documents in December, 2002.

- The Science of Sex and Gender in Human Health Online Course Web Site - This site was developed by NIH and FDA for researchers, clinicians, and members of academia to gain a basic scientific understanding of the major physiological differences between the sexes, the influences these differences have on illness and health outcomes, and the implications for policy, medical research, and health care. Continuing medical education credit is available for physicians

Historical Documents and References:

- 08/02/2000 NIH Guide Notice - NIH Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research - Updated August 2, 2000. Changes to the Guidelines, Sections 'III.B. NIH Phase III Clinical Trials' and 'V. Definitions' are highlighted in **bold** type.

- NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Updated August 2, 2000 - A complete text of the Updated Guidelines, with changes to the Guidelines, Sections 'III.B. NIH Phase III Clinical Trials' and 'V. Definitions' highlighted in **bold** type. The list of NIH Contacts has also been updated.

- 03/18/1994 NIH Guide Notice - NIH Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research.

Weblink: http://grants.nih.gov/grants/funding/women_min/women_min.htm

Appendix E

NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

(Amended, October, 2001)

NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH; Amended, October, 2001.

NOTE: Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm .

SUMMARY: This notice updates the NIH policy on the inclusion of women and minorities as subjects in clinical research. It supercedes the 1994 Federal Register notice (http://grants.nih.gov/grants/guide/notice-files/not94-100.html) and the August 2000 notice in the NIH Guide to Grants and Contracts (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html). It incorporates the definition of clinical research as reported in the 1997 Report of the NIH Director's Panel on Clinical research. Also, this notice provides additional guidance on reporting analyses of sex/gender and racial/ethnic differences in intervention effects for NIH-defined Phase III clinical trials. The guidelines ensure that all NIH-funded clinical research will be carried out in a manner sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups and, particularly in NIH-defined Phase III clinical trials, to examine differential effects on such groups. Since a primary aim of research is to provide scientific evidence leading to a change in health policy or standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently.

In June 2001, NIH adopted the definition of clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research http://www.nih.gov/news/crp/97report/execsum.htm .

EFFECTIVE DATE: This amended policy is effective immediately and applies to all grants and cooperative agreements currently active and to be awarded. Contract solicitations issued as of October 2001 must adhere to the amended policy.

I. LEGISLATIVE BACKGROUND

The NIH Revitalization Act of 1993, PL 103-43, signed into law on June 10, 1993, directed the NIH to establish guidelines for inclusion of women and minorities in clinical research.

The statute states that:

In conducting or supporting clinical research for the purposes of this title, the Director of NIH shall ... ensure that (a) women are included as subjects in each project of such research; and (b) members of minority groups are included in such research. 492B(a)(1)

The statute further directed the NIH to establish guidelines to specify:

(a) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate ......; (b) the manner in which clinical trials are required to be designed and carried out ......; and (c) the operation of outreach programs ...... 492B(d)(1)

The statute defines "clinical research" to include "clinical trials" and states that:

In the case of any clinical trial in which women or members of minority groups will be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial. 492B(c)

Specifically addressing the issue of minority groups, the statute states that:

The term "minority group" includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established...define the terms "minority group" and "subpopulation" for the purposes of the preceding sentence. 492B(g)(2)

The statute speaks specifically to outreach and states that:

The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in the projects of clinical research. 492B(a)(2)

The statute includes a specific provision pertaining to the cost of clinical research and, in particular clinical trials.

(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is (sic) not a permissible consideration in determining whether such inclusion is inappropriate. 492B(d)(2)

(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is (sic) not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality. 492B(d)(2)

Exceptions to the requirement for inclusion of women and minorities are stated in the statute, as follows:

The requirements established regarding women and members of minority groups shall not apply to the project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively-

(1) is inappropriate with respect to the health of the subjects; (2) is inappropriate with respect to the purpose of the research; or (3) is inappropriate under such other circumstances as the Director of NIH may designate. 492B(b)

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between-

(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required. 492B(d)(2)

II. POLICY

A. Inclusion of Women and Minorities as Subjects in Clinical Research

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, 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. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-supported clinical research studies.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. The research plan/proposal should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

B. NIH-defined Phase III Clinical Trials: Planning, Conducting, and Reporting of Analyses for Sex/Gender and Race/Ethnicity Differences.

When an NIH-defined Phase III clinical trial is proposed, evidence must be reviewed to show whether or not clinically important sex/gender and race/ethnicity differences in the intervention effect are to be expected. This evidence may include, but is not limited to, data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies.

Investigators must consider the following when planning, conducting, analyzing, and reporting an NIH-Defined Phase III clinical trial. Based on prior studies, one of the three situations below will apply:

1. Prior Studies Support the Existence of Significant Differences

If the data from prior studies strongly support the existence of significant differences of clinical or public health importance in intervention effect based on sex/gender, racial/ethnic, and relevant subpopulation comparisons, the primary question(s) to be addressed by the proposed NIH-defined Phase III clinical trial and the design of that trial must specifically accommodate this. For example, if men and women are thought to respond differently to an intervention, then the Phase III clinical trial must be designed to answer two separate primary questions, one for men and the other for women, with adequate sample size for each.

The Research Plan (for grant applications) or Proposal (for contract solicitations) must include a description of plans to conduct analyses to detect significant differences in intervention effect (see DEFINITIONS - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable. The final protocol(s) approved by the Institutional Review Board (IRB) must include these plans for analysis. The award will require that for each funded protocol, investigators must report in their annual Progress Report cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences. If final analyses of sex/gender and race/ethnicity are not available at the time of the Final Progress Report or Competing Continuation for the grant, a justification and plan ensuring completion and reporting of the analyses are required. If final analyses are required as part of the contract, these analyses must be included as part of the deliverables. These requirements will be cited in the terms and conditions of all awards for grants, cooperative agreements and contracts supporting NIH-defined Phase III clinical trials.

Inclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions. If these analyses reveal no differences, a brief statement to that effect, indicating the groups and/or subgroups analyzed, will suffice.

2. Prior Studies Support No Significant Differences

If the data from prior studies strongly support no significant differences of clinical or public health importance in intervention effect based on sex/gender, racial/ethnic and/or relevant subpopulation comparisons, then sex/gender and race/ethnicity will not be required as subject selection criteria. However, the inclusion and analysis of sex/gender and/or racial/ethnic subgroups is still strongly encouraged.

3. Prior Studies Neither Support nor Negate Significant Differences

If the data from prior studies neither strongly support nor strongly negate the existence of significant differences of clinical or public health importance in intervention effect based on sex/gender, racial/ethnic, and relevant subpopulation comparisons, then the NIH-defined Phase III clinical trial will be required to include sufficient and appropriate entry of sex/gender and racial/ethnic participants, so that valid analysis of the intervention effects can be performed. However, the trial will not be required to provide high statistical power for these comparisons.

The Research Plan (for grant applications) or Proposal (for contract solicitations) must include a description of plans to conduct valid analysis (see DEFINITIONS - Valid Analysis) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable. The final protocol(s) approved by the Institutional Review Board (IRB) must include these plans for analysis. The award will require that for each funded protocol, investigators must report in their annual Progress Report cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences. If final analyses of sex/gender and race/ethnicity are not available at the time of the Final Progress Report or Competing Continuation for the grant, a justification and plan ensuring completion and reporting of the analyses are required. If final analyses are required as part of the contract, these analyses must be included as part of the deliverables. These requirements will be cited in the terms and conditions of all awards for grants, cooperative agreements and contracts supporting NIH-defined Phase III clinical trials.

Inclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions. If these analyses reveal no differences, a brief statement to that effect, indicating the groups and/or subgroups analyzed, will suffice.

For all three situations, cost is not an acceptable reason for exclusion of women and minorities from clinical trials.

III. ROLES AND RESPONSIBILITIES

While this policy applies to all applicants/offerors for NIH-supported clinical research, certain individuals and groups have special roles and responsibilities with regard to its implementation.

1. NIH Staff

The NIH staff provide educational opportunities for the extramural and intramural communities concerning this policy; monitor its implementation during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.

2. Principal Investigators

Principal investigators should assess the theoretical and/or scientific linkages between sex/gender, race/ethnicity, and their topic of study. Following this assessment, the principal investigator and the applicant/offeror institution will address the policy in each application and proposal, providing the required information on inclusion of women and minorities and their subpopulations in clinical research projects, and any required justifications for exceptions to the policy.

For foreign awards and domestic awards with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

Investigators and their staff(s) are urged to develop appropriate and culturally sensitive outreach programs and activities commensurate with the goals of the study or objectives of the contract. The objective should be to actively recruit and retain the most diverse study population consistent with the purposes of the research project. Indeed, the purpose should be to establish a relationship between the investigator(s) and staff(s) and populations and community(ies) of interest such that mutual benefit is derived for participants in the study. Investigator(s) should take precautionary measures to ensure that ethical issues are considered, such that there is minimal possibility of coercion or undue influence in the incentives or rewards offered in recruiting into or retaining participants in studies.

To assist investigators and potential study participants, NIH staff have prepared educational materials, including a notebook titled the, "NIH Outreach Notebook On the Inclusion of Women and Minorities in Biomedical and Behavioral Research." The notebook as well as the Frequently Asked Questions document, are located at the following URL: http://grants.nih.gov/grants/funding/women_min/women_min.htm

3. Institutional Review Boards (IRBs)

It is the responsibility of the IRBs to address the ethical issues as outlined in Section IV(2) for Principal Investigators. As the IRBs implement the regulation for the protection of human subjects as described in Title 45 CFR Part 46, "Protection of Human Subjects", http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm they must also attend to the guidelines for the inclusion of women and minorities and their subpopulations in clinical research. They should take into account the Food and Drug Administration's "Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs," Vol. 58 Federal Register 39406 http://www.fda.gov/cder/guidance/old036fn.pdf.

4. Peer Review Groups

In conducting peer review for scientific and technical merit, appropriately constituted initial review groups (including study sections), technical evaluation groups, and intramural review panels are instructed, as follows:

- to evaluate the proposed plan for the inclusion of minorities and both genders for appropriate representation or to evaluate the proposed justification when representation is limited or absent,
- to evaluate the proposed exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect to the health of the subjects,
- to evaluate the proposed exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect to the purpose of the research,
- to determine whether the design of clinical trials is adequate to measure differences when warranted,
- to evaluate the plans for valid analysis for NIH-defined Phase III clinical trials,
- to evaluate the plans for recruitment/outreach for study participants, and
- to include these criteria as part of the scientific assessment and evaluation.

The review instructions for grants are available on line at the following URL: http://grants.nih.gov/grants/peer/hs_review_inst.pdf

For contracts, the contracting officer will provide instructions for contract reviewers. Further information on instructions for contracts may be obtained at the following URL: http://oa.od.nih.gov/oamp/index.html.

Or contact:

National Institutes of Health, Division of Acquisition Policy and Evaluation, Office of Acquisition Management and Policy, 6100 Executive Boulevard, Room 6C01, Phone: 301-496-6014Fax: 301- 402-1199

5. NIH Advisory Councils

In addition to other responsibilities for review of projects where the peer review groups have raised questions about the appropriate inclusion of women and minorities, the Advisory Council/Board of each Institute/Center shall prepare biennial reports, for inclusion in the overall NIH Director's biennial report, describing the manner in which the Institute/Center has complied with the provisions of the statute.

6. Institute/Center Directors

Institute/Center Directors and their staff shall ensure compliance with the policy.

7. NIH Director

The NIH Director may approve, on a case-by-case basis, the exclusion of projects, as recommended by the Institute/Center Director, that may be inappropriate to include within the requirements of these guidelines on the basis of circumstances other than the health of the subjects, the purpose of the research, or costs.

IV. DEFINITIONS

Throughout the section of the statute pertaining to the inclusion of women and minorities, terms are used which require definition for the purpose of implementing these guidelines. These terms, drawn directly from the statute, are defined below.

A. Clinical Research

Clinical research is defined as:

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies, (2) Epidemiologic and behavioral studies, (3) Outcomes research and health services research. http://www.nih.gov/news/crp/97report/execsum.htm

B. NIH-defined Clinical Trial

For the purpose of these guidelines, an NIH-defined "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

C. Valid Analysis

The term "valid analysis" means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- allocation of study participants of both sexes/genders (males and females) and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- unbiased evaluation of the outcome(s) of study participants, and
- use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

D. Significant Difference

For purposes of this policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

E. Racial and Ethnic Categories

1. Minority Groups

A minority group is a readily identifiable subset of the U.S. population that is distinguished by racial, ethnic, and/or cultural heritage.

The Office of Management and Budget (OMB) Directive No. 15 http://www.whitehouse.gov/omb/fedreg/ombdir15.html defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. The categories in this classification are social-political constructs and should not be interpreted as anthropological in nature.

When an investigator is planning data collection on race and ethnicity, these categories shall be used. The collection of greater detail is encouraged. However, more detailed items should be designed in a way that they can be aggregated into these required categories. Using respondent self-report or self-identification to collect an individual’s data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation. Respondents shall be offered the opportunity to select more than one racial designation. When data are collected separately, provision shall be made to report the number of respondents in each racial category who are Hispanic or Latino.

The following definitions apply for ethnic categories.

Hispanic or Latino - a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."

Not Hispanic or Latino

The following definitions apply for racial categories.

American Indian or Alaska Native - a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Asian - a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American - a person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or Other Pacific Islander - a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

2. Majority Group

White - a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms "minority groups" and "minority subpopulations" are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

3. Subpopulations

Each racial and ethnic group contains subpopulations that are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one race or ethnicity. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study.

F. Outreach Strategies

These are outreach efforts by investigators and their staff(s) to appropriately recruit and retain populations of interest into research studies. Such efforts should represent a thoughtful and culturally sensitive plan of outreach and generally include involvement of other individuals and organizations relevant to the populations and communities of interest, e.g., family, religious organizations, community leaders and informal gatekeepers, and public and private institutions and organizations. The objective is to establish appropriate lines of communication and cooperation to build mutual trust and cooperation such that both the study and the participants benefit from such collaboration.

V. NIH CONTACTS FOR MORE INFORMATION

The following senior extramural staff from the NIH Institutes and Centers may be contacted for further information about the policy and relevant Institute/Center programs:

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Appendix F

NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research

NIH POLICY ON REPORTING RACE AND ETHNICITY DATA: SUBJECTS IN CLINICAL RESEARCH

Release Date: August 8, 2001

NOTICE: NOT-OD-01-053

National Institutes of Health

POLICY: The NIH has adopted the 1997 Office of Management and Budget (OMB) revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant applications, contract and intramural proposals and for all active research grants, cooperative agreements, contract and intramural projects. The minimum standards are described in the 1997 OMB Directive 15, http://www.whitehouse.gov/OMB/fedreg/ombdir15.html.

SUMMARY: This document provides additional guidance and instruction for using the revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity found in the PHS 398 (rev. 5/01) and PHS 2590 (rev.5/01) instructions and forms http://grants.nih.gov/grants/forms.htm. Comparable information will be provided in research and development contract solicitations and awards for intramural projects. This document should be used in conjunction with the instructions in the PHS 398 and PHS 2590 instructions and forms.

The 1997 OMB revised minimum standards include two ethnic categories (Hispanic or Latino, and Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. Using self-reporting or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

Collection of this information and use of these categories is required for research that meets the NIH definition of clinical research.

EFFECTIVE DATE: This policy applies to all new applications and proposals, annual progress reports, competing continuation applications, competing supplement applications for research grants, contracts, and intramural projects as of January 10, 2002.

I. Revised Minimum Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity

The following are the ethnic and racial definitions for the minimum standard categories (1997 OMB Directive 15).

Ethnic Categories:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term “Spanish origin” can also be used in addition to “Hispanic or Latino.”

Not Hispanic or Latino

Racial Categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Using respondent self-report or self-identification to collect an individual’s data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

When reporting these data in the aggregate, investigators should report: (a) the number of respondents in each ethnic category; (b) the number of respondents who selected only one category for each of the five racial categories; (c) the total number of respondents who selected multiple racial categories reported as the “number selecting more than one race”; and, (d) the number of respondents in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed in a way that they can be aggregated into the required categories for reporting purposes. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. Federal agencies will not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

II. Guidance on Reporting Ethnicity/Race and Sex/Gender in Clinical Research

NIH requires all grants, contracts, and intramural projects conducting clinical research to address the Inclusion of Women and Minorities (see http://grants.nih.gov/grants/funding/women_min/women_min.htm). NIH defines clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

New Applications (type 1), Competing Continuations (type 2), Requests for Proposals, and Intramural Projects

Submitting Applications or Proposals Involving the Collection of New/Additional Data in Clinical Research:

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by ethnic/racial categories and sex/gender. This information must be reported using the newly revised categories and according to the new format provided in the Targeted/Planned Enrollment table
http://grants.nih.gov/grants/funding/phs398/enrollment.pdf

Submitting Applications or Proposals Using Existing Data in Clinical Research with No Plans for Collecting New/Additional Data:

Investigators are instructed to provide plans for the total number of subjects proposed for the study and to provide the distribution by ethnic/racial categories and sex/gender. Under these circumstances, investigators are not required to re-contact subjects solely to comply with the newly revised categories. If the existing data on ethnicity and race allows accurate correspondence with the new categories, the investigator can use the format in the Targeted/Planned Enrollment table. However, if the existing data do not allow accurate correspondence with the new categories, information may be reported using the former categories and according to the format in the 4/98 Version of the Inclusion Table
http://grants.nih.gov/grants/funding/women_min/InclusionOld_Form.pdf

Annual Progress Reports (type 5) and Competing Supplement Applications

In Annual Progress Reports and Competing Supplement Applications, investigators conducting clinical research are required to provide the cumulative total enrollment of subjects to-date (as well as any proposed additions to the Targeted/Planned enrollment in the case of Competing Supplement Applications) and to present the distribution by ethnic/racial categories and sex/gender.

If Data Collection is Ongoing, Such that New Subjects Will be Enrolled and/or Additional Data Will be Collected from Human Subjects:

Investigators may choose to report ethnicity/race and sex/gender sample composition using EITHER the format in the former 4/98 Version of the Inclusion Table OR the new Inclusion Enrollment Report http://grants.nih.gov/grants/funding/phs398/enrollmentreport.pdf [Note: If investigators with on-going data collection choose to report information using the new Inclusion Enrollment Report, they must continue to use this format for the remaining years of the project.]

If Data Collection is Complete, Such that No New/Additional Subject Contact is Planned:

Investigators may EITHER continue to report using the former categories and according to the 4/98 Version of the Inclusion Table, OR, if data allow accurate correspondence with the new categories, use the format in the new Inclusion Enrollment Report.

III. Frequently Asked Questions

1. What categories should I use in my application to estimate race and ethnicity, given the new OMB standards?

Investigators should use the categories described in the PHS 398 instructions and listed in the table “Targeted/Planned Enrollment Table” for New Applications. First, the investigator should report the anticipated total number of males and females to be enrolled by Ethnicity (Hispanic or Latino, Not Hispanic or Latino). Then, the investigator should report the anticipated total number of males and females by Racial Categories (American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American, White). The total number of subjects in the Ethnic Category section of the table should equal the total number of subjects in the Racial Categories section. Investigators do not need to estimate the anticipated number of individuals reporting multiple racial categories (either total number reporting multiple categories or number reporting specific combinations) for New Applications. However, the investigator must follow the OMB guidelines, which include allowing respondents to select multiple race categories, once data collection commences.

2. What if my new application involves analyzing secondary data in which the race and ethnicity categories do not comply with the new OMB guidelines?

If an investigator is using secondary data sets that do not conform to the new OMB guidelines and does not plan to collect any new/additional data from the subjects, this should be noted in the New Application. In this circumstance, the investigator should complete the “Targeted/Planned Enrollment Table” for a New Application and the “Inclusion Enrollment Report” for Continuation Applications, Competing Supplement Applications, and Annual Grant Progress Reports if the data allow. However, if the existing data do not allow accurate correspondence with the new categories, the investigator should report the information using the prior categories and use the 4/98 Version of the Inclusion Table.

3. There are many ways of tabulating the multiple race and ethnicity responses, particularly since the race and ethnicity categories are not mutually exclusive. Do the numbers I report have to "add up"?

The numbers in several parts of the two tables must be the same. In both the "Targeted/Planned Enrollment Table" for a New Application and the "Inclusion Enrollment Report" for Continuation Applications, Competing Supplement Applications, and Annual Progress Reports, the sum in "Ethnic Category: Total of All Subjects" must equal the sum in "Racial Categories: Total of All Subjects." In addition, the "Racial Categories: Total Hispanics or Latinos" in Part B of the "Inclusion Enrollment Report Table" must equal the Total Hispanic or Latino number reported in Part A of the "Inclusion Enrollment Report." Footnotes in the tables clearly identify which numbers must be the same.

4. Can I use the Targeted/Planned Enrollment Table or the Enrollment Inclusion Report to collect data from individuals?

Neither the Targeted/Planned Enrollment Tablet nor the Enrollment Inclusion Report should be used for collecting data from individuals. These tables are only to be used for reporting aggregate data.

To collect data from an individual respondent, investigators should use respondent self-report or self-identification and use two separate questions. The first question should be about ethnicity, followed by a question that provides the option of selecting one or more racial designations. An example of a format for collecting information from an individual can be found in the "Ethnic Origin and Race" section of the Personal Data Form Page in the PHS 398 (rev. 5/01) http://grants.nih.gov/grants/funding/phs398/personal.pdf

5. Can I ask more detailed questions about ethnicity and race than these guidelines indicate?

The revised OMB guidelines provide minimal standards for data collection. Indeed, researchers are encouraged to explore collecting additional types of information on race and ethnicity that will provide additional insights into the relationships between race and ethnicity and health. For example, after asking the ethnicity and then the race questions, researchers may opt to ask study participants who choose multiple categories to identify the group that they identify with primarily. Further questions identifying membership in subpopulations within the ethnic and racial categories provided by OMB may also be considered. The scientific question being addressed in the study should guide investigators' decisions regarding collection of any additional information on ethnicity or race. Information on subpopulations may be reported by listing the information in an attachment to the required table.

6. I have already begun data collection and my categories do not comply with the new OMB standards. Do I need to change my questions on race and ethnicity in the middle of the study?

If data collection has already begun, we do not expect investigators to change their questions on race and ethnicity prior to the completion of the study. For Annual Progress Reports, in this circumstance, investigators should note that the research project was initiated prior to the implementation of the new reporting guidelines. If the data do not accurately correspond with the new categories, the investigator may continue to use the format in the 4/98 Version of the Inclusion Table.

7. I began data collection prior to the new standards, but my race and ethnicity questions comply with the new standards. I submitted my original estimates of the study composition using the old standards. How should I present the data in the progress report?

If you began your data collection prior to the implementation of the new standards but your questions on race and ethnicity comply with the new standards, the choice is left up to the investigator as to how to present the data for Annual Progress Reports. We suggest completion of the new Inclusion Enrollment Report.

8. How should I report race and ethnicity data when my research involves a foreign population?

Investigators are encouraged to design their data collection instruments in ways that allow respondent self-identification of their racial and ethnic affiliation. However, these items should be designed in a way that they can be aggregated into the required categories. Also, the investigator can report on any racial/ethnic subpopulations by listing this information in an attachment to the required table. This may be particularly useful when distinctive subpopulations are relevant to the scientific hypotheses being studied.

When completing the tables, investigators should asterisk and footnote the table indicating that data includes foreign participants. If the aggregated data only includes foreign participants, the investigator should provide information in one table with an asterisk and footnote. However, if the study includes both domestic and foreign participants, we suggest the investigator complete two separate tables -- one for domestic data and one for foreign data, with an asterisk and footnote accompanying the table with foreign data.

9. How do the 1997 OMB revised standards differ from the previous standards?

OMB issued the previous standards for maintaining, collecting, and presenting data on race and ethnicity in 1977. The minimum acceptable categories were: American Indian or Alaska Native; Asian or Pacific Islander; Black, not of Hispanic origin; Hispanic; White, not of Hispanic origin.

The 1997 OMB revised standards now include two ethnic categories (Hispanic or Latino or Not Hispanic or Latino) and five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). When using self-reporting or self-identification to collect data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

Additional Information and NIH Contacts Additional information on NIH policy regarding the Inclusion of Women and Minorities in Clinical Research can be found at the website http://grants.nih.gov/grants/funding/women_min/women_min.htm.

The following senior extramural staff from the NIH Institutes and Centers may be contacted for further information about the policy and relevant Institute/Center programs:

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APPENDIX G

NIH Inclusion Tables for Target and Enrollment Data

- Old Table for Target & Enrollment Data Collection
- New Table for Target Data Collection
- New Table for Enrollment Data Collection

Old Table for Target & Enrollment Data Collection

New Table for Target Data Collection

New Table for Enrollment Data Collection

Appendix H

Comparison of 1977 and 1997 OMB Classifications For Reporting Race and Ethnicity

Comparison of 1977 and 1997 OMB Classifications For Reporting Race and Ethnicity

CLINICAL RESEARCH: NIH defines human clinical research as:

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.

(2) Epidemiologic and behavioral studies.

(3) Outcomes research and health services research.

Appendix I. RACE AND ETHNICITY CATEGORIES INCLUDED IN SUMMARY MINORITY DATA

OLD FORM (1977) versus NEW FORM (1997)		
Race/Ethnicity Category	**Minority Total**	**Minority Total**
	Old Form	**New Form**
OLD FORM: Combined 1977 OMB Race/Ethnicity Categories		
American Indian/Alaska Native	**X**	
Asian/Pacific Islander	**X**	
Black or African American	**X**	
Hispanic, Not White	**X**	
White		
Unknown/Other		

NEW FORM: Separate 1997 OMB Race/Ethnicity Categories		
Part A: Total Enrollment Report		
Ethnic Category		
Hispanic or Latino**		
Not Hispanic or Latino		
Unknown (ethnicity not reported)		
Ethnic Category Total of All Subjects*		
Racial Categories		
American Indian/Alaska Native		**X**
Asian		**X**
Black or African American		**X**
Hawaiian/Pacific Islander		**X**
White		
More Than One Race		**X**
Unknown/Other		
Racial Categories: Total of All Subjects*		

Part B: Hispanic Enrollment by RACE		
American Indian/Alaska Native*		
Asian*		
Black or African American*		
Hawaiian/Pacific Islander*		
White (Hispanic)		**X**
More Than One Race*		
Unknown/Other (Hispanic)		**X**
Racial Categories: Total of Hispanics or Latinos**		

*** The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects"**

**** The "Hispanic or Latino"(Part A) must be equal to "Racial Categories: Total of Hispanics or Latinos"(Part B).**

Note 1. Hispanics are defined by country of origin, and may be identified as belonging to any one, or more than one, race category.

Note 2. The OLD FORM uses the 1977 OMB combined Race and Ethnicity Format, which has mutually exclusive categories, and allows Hispanics to be reported as either "Hispanic, Not White" or "White".

Note 3. The NEW FORM uses the 1997 OMB Race and Ethnicity Categories, with separate reporting for Ethnicity (Hispanic or Latino; Not Hispanic or Latino) and Race. In this format, an individual is classified both by Ethnic Category and by Race Category. Part B of the NEW FORM therefore provides a distribution of only "Hispanics or Latinos" by the five main Race categories. Since minority categories are defined to include both "Hispanic or Latino ethnicity" and non-white racial categories when providing summary totals of minorities, it is necessary to add White Hispanics" and "Unknown/Other Hispanics" based on their ethnicity to the non-white racial categories.

Appendix I

Aggregate Extramural and Intramural Data Tables Funded in FY2006 and Reported in FY2007

Table of Contents: Fiscal Year 2006 Aggregate Data Tables

Domestic and Foreign Clinical Research Reported in FY 2006 and 2007

Table 1A. Aggregate Enrollment Data for Extramural and Intramural Research Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**10,152,590**	**3,112,200**		**30.65%**
%	**58.19%**	**59.66%**		
Males	**6,887,793**	**2,084,383**		**30.26%**
%	**39.48%**	**39.95%**		
Unknown	**408,075**	**20,307**		**4.98%**
%	**2.34%**	**0.39%**		
TOTAL	**17,448,458**	**5,216,890**	**29.90%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**10,914**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **9,816**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	96,979	924,257	1,051,568	33,903	6,172,785	170,128	912,286	9,361,906	7,806,041	739,223	816,642	9,361,906
	0.61%	**5.80%**	**6.60%**	**0.21%**	**38.76%**	**1.07%**	**5.73%**	**58.79%**	**49.02%**	**4.64%**	**5.13%**	**58.79%**
	1.04%	*9.87%*	*11.23%*	*0.36%*	*65.94%*	*1.82%*	*9.74%*	*100.00%*	*83.38%*	*7.90%*	*8.72%*	*100.00%*
	66.69%	68.12%	52.25%	59.32%	59.69%	61.18%	52.66%	58.79%	59.97%	63.23%	46.99%	58.79%
Male	47,890	430,074	953,258	22,891	4,142,378	105,168	460,949	6,162,608	5,179,293	424,302	559,013	6,162,608
	0.30%	**2.70%**	**5.99%**	**0.14%**	**26.01%**	**0.66%**	2.89%	**38.70%**	**32.52%**	**2.66%**	**3.51%**	**38.70%**
	0.78%	*6.98%*	*15.47%*	*0.37%*	*67.22%*	*1.71%*	7.48%	*100.00%*	*84.04%*	*6.89%*	*9.07%*	*100.00%*
	32.93%	31.70%	47.36%	40.05%	40.06%	37.82%	26.61%	38.70%	39.79%	36.29%	32.17%	38.70%
Unknown	548	2,569	7,869	355	26,320	2,772	359,184	399,617	31,790	5,567	362,260	399,617
	0.00%	**0.02%**	**0.05%**	0.00%	**0.17%**	**0.02%**	***2.26%***	**2.51%**	**0.20%**	**0.03%**	**2.27%**	**2.51%**
	0.14%	*0.64%*	*1.97%*	0.09%	*6.59%*	*0.69%*	*89.88%*	*100.00%*	*7.96%*	*1.39%*	*90.65%*	*100.00%*
	0.38%	0.19%	0.39%	0.62%	0.25%	1.00%	20.73%	2.51%	0.24%	0.48%	20.84%	2.51%
Total	145,417	1,356,900	2,012,695	57,149	10,341,483	278,068	1,732,419	15,924,131	13,017,124	1,169,092	1,737,915	15,924,131
	0.91%	**8.52%**	**12.64%**	**0.36%**	**64.94%**	**1.75%**	**10.88%**	**100.00%**	**81.74%**	**7.34%**	**10.91%**	**100.00%**
	0.91%	*8.52%*	*12.64%*	*0.36%*	*64.94%*	*1.75%*	*10.88%*	*100.00%*	*81.74%*	*7.34%*	*10.91%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	20,800	5,576	17,401	2,614	354,148	57,597	281,087	739,223	2,912,070
%	**1.78%**	**0.48%**	**1.49%**	**0.22%**	**30.29%**	**4.93%**	**24.04%**	**63.23%**	**18.29%**
	2.81%	*0.75%*	*2.35%*	*0.35%*	*47.91%*	*7.79%*	*38.02%*	*100.00%*	*31.11%*
	55.35%	75.21%	55.70%	60.65%	65.80%	57.48%	62.45%	63.23%	60.18%
Male	16,606	1,802	13,750	1682	183,416	42,148	164,898	424,302	1,907,595
%	**1.42%**	**0.15%**	**1.18%**	**0.14%**	**15.69%**	**3.61%**	**14.10%**	**36.29%**	**11.98%**
	3.91%	*0.42%*	*3.24%*	*0.40%*	*43.23%*	*9.93%*	*38.86%*	*100.00%*	*30.95%*
	44.19%	24.31%	44.02%	39.03%	34.08%	42.07%	36.63%	36.29%	39.42%
Unknown	175	36	88	14	652	452	4,150	5,567	18,915
%	**0.01%**	**0.00%**	**0.01%**	**0.00%**	**0.06%**	**0.04%**	**0.35%**	**0.48%**	**0.12%**
	3.14%	*0.65%*	*1.58%*	*0.25%*	*11.71%*	*8.12%*	*74.55%*	*100.00%*	*4.73%*
	0.47%	0.49%	0.28%	0.32%	0.12%	0.45%	0.92%	0.48%	0.39%
TOTAL	37,581	7,414	31,239	4,310	538,216	100,197	450,135	1,169,092	4,838,580
	3.21%	**0.63%**	**2.67%**	**0.37%**	**46.04%**	**8.57%**	**38.50%**	**100.00%**	**30.39%**
	3.21%	*0.63%*	*2.67%*	*0.37%*	*46.04%*	*8.57%*	*38.50%*	*100.00%*	*30.39%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 1A

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

Number of Protocols with Enrollment Data: **1,098**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	2,680	26,937	127,508	43,005	567,301	23,253	790,684	200,130
	0.18%	**1.77%**	**8.36%**	**2.82%**	**37.22%**	**1.53%**	**51.87%**	**13.13%**
	0.34%	*3.41%*	*16.13%*	*5.44%*	*71.75%*	*2.94%*	*100.00%*	*25.31%*
	49.89%	52.06%	53.57%	51.69%	51.70%	47.82%	51.87%	52.90%
Male	2,549	24,637	109,917	39,685	528,350	20,047	725,185	176,788
	0.17%	**1.62%**	**7.21%**	**2.60%**	**34.66%**	**1.32%**	**47.57%**	**11.60%**
	0.35%	*3.40%*	*15.16%*	*5.47%*	*72.86%*	*2.76%*	*100.00%*	*24.38%*
	47.45%	47.62%	46.18%	47.70%	48.15%	41.22%	47.57%	46.73%
Unknown	143	168	579	502	1,736	5,330	8,458	1392
	0.01%	**0.01%**	**0.04%**	**0.03%**	**0.11%**	**0.35%**	**0.55%**	**0.09%**
	1.69%	*1.99%*	*6.85%*	*5.94%*	*20.52%*	*63.02%*	*100.00%*	*16.46%*
	2.66%	0.32%	0.24%	0.60%	0.16%	10.96%	0.55%	0.37%
Total	5,372	51,742	238,004	83,192	1,097,387	48,630	1,524,327	378,310
	0.35%	**3.39%**	**15.61%**	**5.46%**	**71.99%**	**3.19%**	**100.00%**	**24.82%**
	0.35%	*3.39%*	*15.61%*	*5.46%*	*71.99%*	*3.19%*	*100.00%*	*24.82%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender
In FY2007 more females (10,152,590; 58.19%) than males (6,887,793; 39.48%) were enrolled in aggregate extramural and intramural research protocols.
More minority females (3,112,200; 59.66%) than minority males (2,084,383; 39.95%) were enrolled in aggregate extramural and intramural research protocols.

Race
Approximately 29.90% (5,216,890) of participants in aggregate extramural and intramural research (17,448,458 total) were classified as U.S. minorities.
Largest identified racial group was White at 71.99% following the 1977 OMB standards and 64.94% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 15.61% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 12.64% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.35%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.36%.

Ethnicity
7.34% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 46.04% (2nd highest category is Unknown/Other at 38.50%)
Smallest identified racial group was Hawaiian/Pacific Islander at 0.37%.
Of the 1,169,092 participants, 63.23% were women and 36.29% were men.
5.46% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 2A. Aggregate Enrollment Data for Extramural and Intramural Phase III Research Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**324,694**	**143,482**		**44.19%**
%	**54.92%**	**58.58%**		
Males	**249,633**	**100,656**		**40.32%**
%	**42.23%**	**41.10%**		
Unknown	**16,832**	**794**		**4.72%**
%	**2.85%**	**0.32%**		
TOTAL	**591,159**	**244,932**	**41.43%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **621**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **424**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	5,080	22,248	45,603	335	70,059	2,088	63,705	209,118	131,464	54,936	22,718	209,118
	1.33%	**5.83%**	**11.95%**	**0.09%**	**18.36%**	**0.55%**	**16.70%**	**54.81%**	**34.46%**	**14.40%**	**5.95%**	**54.81%**
	2.43%	*10.64%*	*21.81%*	*0.16%*	*33.50%*	*1.00%*	*30.46%*	*100.00%*	*62.87%*	*26.27%*	*10.86%*	*100.00%*
	54.33%	46.97%	53.99%	60.36%	52.68%	50.37%	62.08%	54.81%	51.62%	76.70%	41.16%	54.81%
Male	4,225	25,081	38,460	218	62,624	1,985	22,980	155,573	122,403	16,419	16,751	155,573
	1.11%	**6.57%**	**10.08%**	**0.06%**	**16.42%**	**0.52%**	6.02%	**40.78%**	**32.08%**	**4.30%**	**4.39%**	**40.78%**
	2.72%	*16.12%*	*24.72%*	*0.14%*	*40.25%*	*1.28%*	14.77%	*100.00%*	*78.68%*	*10.55%*	*10.77%*	*100.00%*
	45.18%	52.95%	45.53%	39.28%	47.09%	47.89%	22.39%	40.78%	48.06%	22.92%	30.35%	40.78%
Unknown	46	35	405	2	319	72	15,932	16,811	825	267	15,719	16,811
	0.01%	**0.01%**	**0.11%**	0.00%	**0.08%**	**0.02%**	***4.18%***	**4.41%**	**0.22%**	**0.07%**	**4.12%**	**4.41%**
	0.27%	*0.21%*	*2.41%*	0.01%	*1.90%*	*0.43%*	*94.77%*	*100.00%*	*4.91%*	*1.59%*	*93.50%*	*100.00%*
	0.49%	0.07%	0.48%	0.36%	0.24%	1.74%	15.53%	4.41%	0.32%	0.37%	28.48%	4.41%
Total	9,351	47,364	84,468	555	133,002	4,145	102,617	381,502	254,692	71,622	55,188	381,502
	2.45%	**12.42%**	**22.14%**	**0.15%**	**34.86%**	**1.09%**	**26.90%**	**100.00%**	**66.76%**	**18.77%**	**14.47%**	**100.00%**
	2.45%	*12.42%*	*22.14%*	*0.15%*	*34.86%*	*1.09%*	*26.90%*	*100.00%*	*66.76%*	*18.77%*	*14.47%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	3,867	24	281	19	4,946	175	45,624	54,936	125,924
	5.40%	**0.03%**	**0.39%**	**0.03%**	**6.91%**	**0.24%**	**63.70%**	**76.70%**	**33.01%**
	7.04%	*0.04%*	*0.51%*	*0.03%*	*9.00%*	*0.32%*	*83.05%*	*100.00%*	*60.22%*
	52.73%	53.33%	61.35%	79.17%	66.57%	54.35%	81.46%	76.70%	60.16%
Male	3,433	21	177	5	2,484	146	10,153	16,419	82,606
	4.79%	**0.03%**	**0.25%**	**0.01%**	**3.47%**	**0.20%**	**14.18%**	**22.92%**	**21.65%**
	20.91%	*0.13%*	*1.08%*	*0.03%*	*15.13%*	*0.89%*	*61.84%*	*100.00%*	*53.10%*
	46.82%	46.67%	38.65%	20.83%	33.43%	45.34%	18.13%	22.92%	39.46%
Unknown	33	0	0	0	0	1	233	267	793
	0.05%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.33%**	**0.37%**	**0.21%**
	12.36%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.37%*	*87.27%*	*100.00%*	*4.72%*
	0.45%	0.00%	0.00%	0.00%	0.00%	0.31%	0.42%	0.37%	0.38%
TOTAL	7,333	45	458	24	7,430	322	56,010	71,622	209,323
	10.24%	**0.06%**	**0.64%**	**0.03%**	**10.37%**	**0.45%**	**78.20%**	**100.00%**	**54.87%**
	10.24%	*0.06%*	*0.64%*	*0.03%*	*10.37%*	*0.45%*	*78.20%*	*100.00%*	*54.87%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 2A

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

Number of Protocols with Enrollment Data: **197**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	421	2,359	10,637	4,141	95,830	2,188	115,576	17,558
	0.20%	**1.13%**	**5.07%**	**1.98%**	**45.71%**	**1.04%**	**55.13%**	**8.37%**
	0.36%	*2.04%*	*9.20%*	*3.58%*	*82.92%*	*1.89%*	*100.00%*	*15.19%*
	56.06%	59.83%	49.29%	44.37%	56.44%	51.37%	55.13%	49.31%
Male	330	1,584	10,944	5,192	73,943	2,067	94,060	18,050
	0.16%	**0.76%**	**5.22%**	**2.48%**	**35.27%**	**0.99%**	**44.86%**	**8.61%**
	0.35%	*1.68%*	*11.64%*	*5.52%*	*78.61%*	*2.20%*	*100.00%*	*19.19%*
	43.94%	40.17%	50.71%	55.63%	43.55%	48.53%	44.86%	50.69%
Unknown	0	0	1	0	16	4	21	1
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*4.76%*	*0.00%*	*76.19%*	*19.05%*	*100.00%*	*4.76%*
	0.00%	0.00%	0.00%	0.00%	0.01%	0.09%	0.01%	0.00%
Total	751	3,943	21,582	9,333	169,789	4,259	209,657	35,609
	0.36%	**1.88%**	**10.29%**	**4.45%**	**80.98%**	**2.03%**	**100.00%**	**16.98%**
	0.36%	*1.88%*	*10.29%*	*4.45%*	*80.98%*	*2.03%*	*100.00%*	*16.98%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

In FY2007 more females (324,694; 54.92%) than males (249,633; 42.23%) were enrolled in aggregate extramural and intramural Phase III research protocols.
More minority females (143,482; 58.58%) than minority males (100,656; 41.10%) were enrolled in aggregate extramural and intramural Phase III research protocols.

Race

Approximately 41.43% (244,932) of participants in aggregate extramural and intramural Phase III research (591,159 total) were classified as U.S. minorities.
Largest identified racial group was White at 80.98% following the 1977 OMB standards and 34.86% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 10.29% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 22.14% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.36%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.15%.

Ethnicity

18.77% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 78.20% (2nd largest category is White at 10.37%)
Smallest identified racial group was Hawaiian/Pacific Islander at 0.03%. (**Note:** this is a change from FY2006 when the smallest identified racial group was Asian)
Of the 71,622 participants, 76.70% were women and 22.92% were men.
4.45% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 3A. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**8,652,645**	**2,716,478**		**31.39%**
%	**61.84%**	**61.76%**		
Males	**4,971,895**	**1,663,177**		**33.45%**
%	**35.54%**	**37.81%**		
Unknown	**366,742**	**18,789**		**5.12%**
%	**2.62%**	**0.43%**		
TOTAL	**13,991,282**	**4,398,444**	**31.44%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **9,362**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **8,713**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	86,249	799,997	996,531	30,436	5,456,346	160,305	847,000	8,376,864	6,917,630	683,000	776,234	8,376,864
	0.64%	**5.93%**	**7.39%**	**0.23%**	**40.46%**	**1.19%**	**6.28%**	**62.12%**	**51.30%**	**5.07%**	**5.76%**	**62.12%**
	1.03%	*9.55%*	*11.90%*	*0.36%*	*65.14%*	*1.91%*	*10.11%*	*100.00%*	*82.58%*	*8.15%*	*9.27%*	*100.00%*
	69.75%	68.38%	56.12%	57.28%	63.17%	60.63%	58.00%	62.12%	63.28%	64.02%	52.22%	62.12%
Male	36,876	368,138	771,181	22,345	3,157,379	102,084	291,234	4,749,237	3,985,057	378,293	385,887	4,749,237
	0.27%	**2.73%**	**5.72%**	**0.17%**	**23.41%**	**0.76%**	2.16%	**35.22%**	**29.55%**	**2.81%**	**2.86%**	**35.22%**
	0.78%	*7.75%*	*16.24%*	*0.47%*	*66.48%*	*2.15%*	6.13%	*100.00%*	*83.91%*	*7.97%*	*8.13%*	*100.00%*
	29.82%	31.46%	43.43%	42.05%	36.55%	38.61%	19.94%	35.22%	36.46%	35.46%	25.96%	35.22%
Unknown	526	1,863	7,854	355	23,725	2,003	322,015	358,341	28,501	5,547	324,293	358,341
	0.00%	**0.01%**	**0.06%**	0.00%	**0.18%**	**0.01%**	***2.39%***	**2.66%**	**0.21%**	**0.04%**	**2.40%**	**2.66%**
	0.15%	*0.52%*	*2.19%*	0.10%	*6.62%*	*0.56%*	*89.86%*	*100.00%*	*7.95%*	*1.55%*	*90.50%*	*100.00%*
	0.43%	0.16%	0.44%	0.67%	0.27%	0.76%	22.05%	2.66%	0.26%	0.52%	21.82%	2.66%
Total	123,651	1,169,998	1,775,566	53,136	8,637,450	264,392	1,460,249	13,484,442	10,931,188	1,066,840	1,486,414	13,484,442
	0.92%	**8.68%**	**13.17%**	**0.39%**	**64.05%**	**1.96%**	**10.83%**	**100.00%**	**81.07%**	**7.91%**	**11.02%**	**100.00%**
	0.92%	*8.68%*	*13.17%*	*0.39%*	*64.05%*	*1.96%*	*10.83%*	*100.00%*	*81.07%*	*7.91%*	*11.02%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	19,600	5,562	17,069	2,574	328,520	55,722	253,953	683,000	2,655,991
	1.84%	**0.52%**	**1.60%**	**0.24%**	**30.79%**	**5.22%**	**23.80%**	**64.02%**	**19.70%**
	2.87%	*0.81%*	*2.50%*	*0.38%*	*48.10%*	*8.16%*	*37.18%*	*100.00%*	*31.71%*
	55.79%	75.35%	60.43%	60.52%	68.30%	57.60%	61.33%	64.02%	62.03%
Male	15,372	1,784	11,091	1665	151,846	40,563	155,972	378,293	1,608,442
	1.44%	**0.17%**	**1.04%**	**0.16%**	**14.23%**	**3.80%**	**14.62%**	**35.46%**	**11.93%**
	4.06%	*0.47%*	*2.93%*	*0.44%*	*40.14%*	*10.72%*	*41.23%*	*100.00%*	*33.87%*
	43.76%	24.17%	39.26%	39.15%	31.57%	41.93%	37.67%	35.46%	37.56%
Unknown	159	36	88	14	652	452	4,146	5,547	17,399
	0.01%	**0.00%**	**0.01%**	**0.00%**	**0.06%**	**0.04%**	**0.39%**	**0.52%**	**0.13%**
	2.87%	*0.65%*	*1.59%*	*0.25%*	*11.75%*	*8.15%*	*74.74%*	*100.00%*	*4.86%*
	0.45%	0.49%	0.31%	0.33%	0.14%	0.47%	1.00%	0.52%	0.41%
TOTAL	35,131	7,382	28,248	4,253	481,018	96,737	414,071	1,066,840	4,281,832
	3.29%	**0.69%**	**2.65%**	**0.40%**	**45.09%**	**9.07%**	**38.81%**	**100.00%**	**31.75%**
	3.29%	*0.69%*	*2.65%*	*0.40%*	*45.09%*	*9.07%*	*38.81%*	*100.00%*	*31.75%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 3A

Number of Protocols with Enrollment Data: **649**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	1,804	7,845	30,985	19,853	198,153	17,141	275,781	60,487
	0.36%	**1.55%**	**6.11%**	**3.92%**	**39.10%**	**3.38%**	**54.41%**	**11.93%**
	0.65%	*2.84%*	*11.24%*	*7.20%*	*71.85%*	*6.22%*	*100.00%*	*21.93%*
	49.10%	53.55%	52.52%	50.52%	56.14%	45.98%	54.41%	51.87%
Male	1,727	6,638	27,428	18,942	153,077	14,846	222,658	54,735
	0.34%	**1.31%**	**5.41%**	**3.74%**	**30.20%**	**2.93%**	**43.93%**	**10.80%**
	0.78%	*2.98%*	*12.32%*	*8.51%*	*68.75%*	*6.67%*	*100.00%*	*24.58%*
	47.01%	45.31%	46.50%	48.20%	43.37%	39.82%	43.93%	46.94%
Unknown	143	168	578	501	1,717	5,294	8,401	1390
	0.028%	**0.03%**	**0.11%**	**0.10%**	**0.34%**	**1.04%**	**1.66%**	**0.27%**
	1.70%	*2.00%*	*6.88%*	*5.96%*	*20.44%*	*63.02%*	*100.00%*	*16.55%*
	3.89%	1.15%	0.98%	1.27%	0.49%	14.20%	1.66%	1.19%
Total	3,674	14,651	58,991	39,296	352,947	37,281	506,840	116,612
	0.72%	**2.89%**	**11.64%**	**7.75%**	**69.64%**	**7.36%**	**100.00%**	**23.01%**
	0.72%	*2.89%*	*11.64%*	*7.75%*	*69.64%*	*7.36%*	*100.00%*	*23.01%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

In FY2007 more females (8,652,645; 61.84%) than males (4,971,895; 35.54%) were enrolled in aggregate extramural research protocols.
More minority females (2,716,4781; 61.76%) than minority males (1,663,177; 37.81%) were enrolled in aggregate extramural research protocols.

Race

Approximately 31.44% (4,398,444) of participants in aggregate extramural research (16,979,004 total) were classified as U.S. minorities.
Largest identified racial group was White at 69.64% following the 1977 OMB standards and 64.05% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 11.64% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 13.17% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.72%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.39%.

Ethnicity

7.91% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 45.09% (2nd largest category is Unknown/Other at 38.81%)
Smallest identified racial group was Hawaiian/Pacific Islanders at 0.40%
Of the 1,066,840 participants, 64.02% were women and 35.46% were men.
7.75% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 4A. Aggregate Enrollment Data for <u>Extramural Research Protocols Excluding Male-Only and Female-Only Protocols</u> Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**4,435,292**	**1,645,545**		**37.10%**
%	**46.45%**	**50.36%**		
Males	**4,761,326**	**1,606,976**		**33.75%**
%	**49.87%**	**49.18%**		
Unknown	**350,892**	**14,743**		**4.20%**
%	**3.68%**	**0.45%**		
TOTAL	**9,547,510**	**3,267,264**	**34.22%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	7,651

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **7,158**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	43,409	408,811	666,263	28,253	2,635,011	134,098	338,551	4,254,396	3,523,627	395,681	335,088	4,254,396
	0.47%	**4.45%**	**7.26%**	**0.31%**	**28.71%**	**1.46%**	**3.69%**	**46.36%**	**38.39%**	**4.31%**	**3.65%**	**46.36%**
	1.02%	*9.61%*	*15.66%*	*0.66%*	*61.94%*	*3.15%*	*7.96%*	*100.00%*	*82.82%*	*9.30%*	*7.88%*	*100.00%*
	54.07%	53.12%	47.06%	55.61%	46.35%	57.38%	35.94%	46.36%	47.43%	51.37%	34.26%	46.36%
Male	36,344	359,148	744,527	22,194	3,034,321	98,583	285,602	4,580,719	3,883,627	369,165	327,927	4,580,719
	0.40%	**3.91%**	**8.11%**	**0.24%**	**33.06%**	**1.07%**	3.11%	**49.91%**	**42.32%**	**4.02%**	**3.57%**	**49.91%**
	0.79%	*7.84%*	*16.25%*	*0.48%*	*66.24%*	*2.15%*	6.23%	*100.00%*	*84.78%*	*8.06%*	*7.16%*	*100.00%*
	45.27%	46.67%	52.59%	43.69%	53.37%	42.18%	30.32%	49.91%	52.27%	47.92%	33.53%	49.91%
Unknown	526	1,648	5,062	355	15,996	1,028	317,876	342,491	22,055	5,483	314,953	342,491
	0.01%	**0.02%**	**0.06%**	0.00%	**0.17%**	**0.01%**	***3.46%***	**3.73%**	**0.24%**	**0.06%**	**3.43%**	**3.73%**
	0.15%	*0.48%*	*1.48%*	0.10%	*4.67%*	*0.30%*	*92.81%*	*100.00%*	*6.44%*	*1.60%*	*91.96%*	*100.00%*
	0.66%	0.21%	0.36%	0.70%	0.28%	0.44%	33.74%	3.73%	0.30%	0.71%	32.20%	3.73%
Total	80,279	769,607	1,415,852	50,802	5,685,328	233,709	942,029	9,177,606	7,429,309	770,329	977,968	9,177,606
	0.87%	**8.39%**	**15.43%**	**0.55%**	**61.95%**	**2.55%**	**10.26%**	**100.00%**	**80.95%**	**8.39%**	**10.66%**	**100.00%**
	0.87%	*8.39%*	*15.43%*	*0.55%*	*61.95%*	*2.55%*	*10.26%*	*100.00%*	*80.95%*	*8.39%*	*10.66%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	14,546	1,914	12,613	2019	166,532	46,927	151,130	395,681	1,598,496
	1.89%	**0.25%**	**1.64%**	**0.26%**	**21.62%**	**6.09%**	**19.62%**	**51.37%**	**17.42%**
	3.68%	*0.48%*	*3.19%*	*0.51%*	*42.09%*	*11.86%*	*38.19%*	*100.00%*	*37.57%*
	48.65%	51.48%	53.75%	54.76%	52.98%	54.58%	48.87%	51.37%	50.37%
Male	15,195	1,768	10,764	1654	147,159	38,607	154,018	369,165	1,561,973
	1.97%	**0.23%**	**1.40%**	**0.21%**	**19.10%**	**5.01%**	**19.99%**	**47.92%**	**17.02%**
	4.12%	*0.48%*	*2.92%*	*0.45%*	*39.86%*	*10.46%*	*41.72%*	*100.00%*	*34.10%*
	50.82%	47.55%	45.87%	44.86%	46.81%	44.90%	49.81%	47.92%	49.21%
Unknown	159	36	88	14	652	452	4,082	5,483	13,353
	0.02%	**0.00%**	**0.01%**	**0.00%**	**0.08%**	**0.06%**	**0.53%**	**0.71%**	**0.15%**
	2.90%	*0.66%*	*1.60%*	*0.26%*	*11.89%*	*8.24%*	*74.45%*	*100.00%*	*3.90%*
	0.53%	0.97%	0.38%	0.38%	0.21%	0.53%	1.32%	0.71%	0.42%
TOTAL	29,900	3,718	23,465	3,687	314,343	85,986	309,230	770,329	3,173,822
	3.88%	**0.48%**	**3.05%**	**0.48%**	**40.81%**	**11.16%**	**40.14%**	**100.00%**	**34.58%**
	3.88%	*0.48%*	*3.05%*	*0.48%*	*40.81%*	*11.16%*	*40.14%*	*100.00%*	*34.58%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 4A

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

Number of Protocols with Enrollment Data: **493**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	1,426	6,160	22,464	16,999	118,059	15,788	180,896	47,049
	0.39%	**1.67%**	**6.07%**	**4.60%**	**31.92%**	**4.27%**	**48.90%**	**12.72%**
	0.79%	*3.41%*	*12.42%*	*9.40%*	*65.26%*	*8.73%*	*100.00%*	*26.01%*
	45.30%	49.49%	51.10%	50.16%	48.92%	44.94%	48.90%	50.35%
Male	1,579	6,119	20,917	16,388	121,551	14,053	180,607	45,003
	0.43%	**1.65%**	**5.65%**	**4.43%**	**32.86%**	**3.80%**	**48.83%**	**12.17%**
	0.87%	*3.39%*	*11.58%*	*9.07%*	*67.30%*	*7.78%*	*100.00%*	*24.92%*
	50.16%	49.16%	47.58%	48.36%	50.37%	40.00%	48.83%	48.16%
Unknown	143	168	578	501	1,717	5,294	8,401	1390
	0.039%	**0.05%**	**0.16%**	**0.14%**	**0.46%**	**1.43%**	**2.27%**	**0.38%**
	1.70%	*2.00%*	*6.88%*	*5.96%*	*20.44%*	*63.02%*	*100.00%*	*16.55%*
	4.54%	1.35%	1.31%	1.48%	0.71%	15.07%	2.27%	1.49%
Total	3,148	12,447	43,959	33,888	241,327	35,135	369,904	93,442
	0.85%	**3.36%**	**11.88%**	**9.16%**	**65.24%**	**9.50%**	**100.00%**	**25.26%**
	0.85%	*3.36%*	*11.88%*	*9.16%*	*65.24%*	*9.50%*	*100.00%*	*25.26%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments: Reference Table 2A

Sex/Gender

Excluding sex-specific studies, the number of males (4,761,326 or 49.87%) exceeded the number of females (4,435,292 or 46.45%) enrolled in Extramural Research Protocols.
Excluding sex-specific studies, the number of minority females (1,645,545 or 50.36%) exceeded the number of minority males (1,606,976 or 49.18%) enrolled in Extramural Research Protocols.

Race

Approximately 34.22% (3,267,264) of participants in aggregate Extramural Research Protocols (9,547,510 total) were classified as U.S. minorities.
Largest identified racial group was White at 65.24% following the 1977 OMB standards and 61.95% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 11.88% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 15.43% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.85%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.55%.

Ethnicity

8.39% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 40.81% (2nd largest category was Unknown/Other at 40.14%)
Smallest identified racial groups were Hawaiian/Pacific Islander and Asian, both at 0.48%.
Of the 770,329 participants, 51.37% were women and 47.92% were men.
9.16% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 5A. Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	301,735	134,342		44.52%
%	55.10%	57.64%		
Males	229,062	97,934		42.75%
%	41.83%	42.02%		
Unknown	16,830	794		4.72%
%	3.07%	0.34%		
TOTAL	547,627	233,070	42.56%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 585

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 399

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	5,069	22,153	45,059	263	64,693	1,822	55,182	194,241	125,448	47,629	21,164	194,241
	1.41%	**6.15%**	**12.51%**	**0.07%**	**17.96%**	**0.51%**	**15.32%**	**53.91%**	**34.82%**	**13.22%**	**5.87%**	**53.91%**
	2.61%	*11.40%*	*23.20%*	*0.14%*	*33.31%*	*0.94%*	*28.41%*	*100.00%*	*64.58%*	*24.52%*	*10.90%*	*100.00%*
	54.34%	46.98%	53.88%	54.45%	52.36%	49.70%	59.67%	53.91%	51.37%	74.34%	40.66%	53.91%
Male	4,213	24,969	38,165	218	58,552	1,772	21,366	149,255	117,914	16,176	15,165	149,255
	1.17%	**6.93%**	**10.59%**	**0.06%**	**16.25%**	**0.49%**	5.93%	**41.42%**	**32.73%**	**4.49%**	**4.21%**	**41.42%**
	2.82%	*16.73%*	*25.57%*	*0.15%*	*39.23%*	*1.19%*	14.32%	*100.00%*	*79.00%*	*10.84%*	*10.16%*	*100.00%*
	45.17%	52.95%	45.64%	45.13%	47.39%	48.34%	23.10%	41.42%	48.29%	25.25%	29.14%	41.42%
Unknown	46	35	405	2	319	72	15,930	16,809	825	267	15,717	16,809
	0.01%	**0.01%**	**0.11%**	0.00%	**0.09%**	**0.02%**	*4.42%*	**4.67%**	**0.23%**	**0.07%**	**4.36%**	**4.67%**
	0.27%	*0.21%*	*2.41%*	0.01%	*1.90%*	*0.43%*	*94.77%*	*100.00%*	*4.91%*	*1.59%*	*93.50%*	*100.00%*
	0.49%	0.07%	0.48%	0.41%	0.26%	1.96%	17.23%	4.67%	0.34%	0.42%	30.20%	4.67%
Total	9,328	47,157	83,629	483	123,564	3,666	92,478	360,305	244,187	64,072	52,046	360,305
	2.59%	**13.09%**	**23.21%**	**0.13%**	**34.29%**	**1.02%**	**25.67%**	**100.00%**	**67.77%**	**17.78%**	**14.44%**	**100.00%**
	2.59%	*13.09%*	*23.21%*	*0.13%*	*34.29%*	*1.02%*	*25.67%*	*100.00%*	*67.77%*	*17.78%*	*14.44%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	3,847	21	234	16	4,492	174	38,845	47,629	117,703
	6.00%	**0.03%**	**0.37%**	**0.02%**	**7.01%**	**0.27%**	**60.63%**	**74.34%**	**32.67%**
	8.08%	*0.04%*	*0.49%*	*0.03%*	*9.43%*	*0.37%*	*81.56%*	*100.00%*	*60.60%*
	52.60%	50.00%	56.93%	76.19%	64.41%	54.21%	79.29%	74.34%	58.78%
Male	3433	21	177	5	2,482	146	9,912	16,176	81,731
	5.36%	**0.03%**	**0.28%**	**0.01%**	**3.87%**	**0.23%**	**15.47%**	**25.25%**	**22.68%**
	21.22%	*0.13%*	*1.09%*	*0.03%*	*15.34%*	*0.90%*	*61.28%*	*100.00%*	*54.76%*
	46.94%	50.00%	43.07%	23.81%	35.59%	45.48%	20.23%	25.25%	40.82%
Unknown	33	0	0	0	0	1	233	267	793
	0.05%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.36%**	**0.42%**	**0.22%**
	12.36%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.37%*	*87.27%*	*100.00%*	*4.72%*
	0.45%	0.00%	0.00%	0.00%	0.00%	0.31%	0.48%	0.42%	0.40%
TOTAL	7,313	42	411	21	6,974	321	48,990	64,072	200,227
	11.41%	**0.07%**	**0.64%**	**0.03%**	**10.88%**	**0.50%**	**76.46%**	**100.00%**	**55.57%**
	11.41%	*0.07%*	*0.64%*	*0.03%*	*10.88%*	*0.50%*	*76.46%*	*100.00%*	*55.57%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 5A

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

Number of Protocols with Enrollment Data: **186**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
	415	2,190	10,067	3,967	88,698	2,157	107,494	16,639
	0.22%	**1.17%**	**5.37%**	**2.12%**	**47.35%**	**1.15%**	**57.38%**	**8.88%**
	0.39%	*2.04%*	*9.37%*	*3.69%*	*82.51%*	*2.01%*	*100.00%*	*15.48%*
	57.24%	62.64%	50.83%	44.99%	59.01%	51.80%	57.38%	50.66%
Male	310	1,306	9,736	4,851	61,601	2,003	79,807	16,203
	0.17%	**0.70%**	**5.20%**	**2.59%**	**32.89%**	**1.07%**	**42.60%**	**8.65%**
	0.39%	*1.64%*	*12.20%*	*6.08%*	*77.19%*	*2.51%*	*100.00%*	*20.30%*
	42.76%	37.36%	49.16%	55.01%	40.98%	48.10%	42.60%	49.33%
Unknown	0	0	1	0	16	4	21	1
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*4.76%*	*0.00%*	*76.19%*	*19.05%*	*100.00%*	*4.76%*
	0.00%	0.00%	0.01%	0.00%	0.01%	0.10%	0.01%	0.00%
Total	725	3,496	19,804	8,818	150,315	4,164	187,322	32,843
	0.39%	**1.87%**	**10.57%**	**4.71%**	**80.24%**	**2.22%**	**100.00%**	**17.53%**
	0.39%	*1.87%*	*10.57%*	*4.71%*	*80.24%*	*2.22%*	*100.00%*	*17.53%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (301,735 or 55.10%) than males (229,062 or 41.83%) were enrolled in aggregate Pase III Extramural Research Protocols.
More minority females (134,342 or 57.64%) than males (97,934 or 42.02%) were enrolled in aggregate Pase III Extramural Research Protocols.

Race

Approximately 42.56% (233,070) of participants in aggregate Phase III Extramural Research (547,627 total) were classified as U.S. minorities.
Largest identified racial group was White at 80.24% following the 1977 OMB standards and 32.99% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 10.57% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 23.21% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.39%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.13%.

Ethnicity

About 17.78% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 76.46% (2nd largest category was American Indian/Alaska Native at 11.41%)
Smallest identified racial group was Hawaiian/Pacific Islander at 0.07%.
Of the 187,322 participants, 57.38% were women and 42.60% were men.
About 4.71% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 6A. Aggregate Enrollment Data for Extramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	171,908	93,409		54.34%
%	48.41%	52.64%		
Males	167,127	83,241		49.81%
%	47.06%	46.91%		
Unknown	16,087	794		4.94%
%	4.53%	0.45%		
TOTAL	355,122	177,444	49.97%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	452

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	330

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	4,845	20,155	37,682	186	37,546	1,488	23,282	125,184	92,229	13,046	19,909	125,184
	1.80%	7.50%	14.02%	0.07%	13.97%	0.55%	8.66%	46.59%	34.32%	4.86%	7.41%	46.59%
	3.87%	16.10%	30.10%	0.15%	29.99%	1.19%	18.60%	100.00%	73.67%	10.42%	15.90%	100.00%
	53.38%	45.47%	52.06%	45.93%	46.92%	45.95%	39.29%	46.59%	48.57%	45.11%	39.91%	46.59%
Male	4,186	24,136	34,292	217	42,162	1,678	20,791	127,462	96,855	15,606	15,001	127,462
	1.56%	8.98%	12.76%	0.08%	15.69%	0.62%	7.74%	47.43%	36.04%	5.81%	5.58%	47.43%
	3.28%	18.94%	26.90%	0.17%	33.08%	1.32%	16.31%	100.00%	75.99%	12.24%	11.77%	100.00%
	46.12%	54.45%	47.38%	53.58%	52.69%	51.82%	35.08%	47.43%	51.00%	53.96%	30.07%	47.43%
Unknown	46	35	405	2	318	72	15,188	16,066	824	267	14,975	16,066
	0.02%	0.01%	0.15%	0.00%	0.12%	0.03%	5.65%	5.98%	0.31%	0.10%	5.57%	5.98%
	0.29%	0.22%	2.52%	0.01%	1.98%	0.45%	94.54%	100.00%	5.13%	1.66%	93.21%	100.00%
	0.51%	0.08%	0.56%	0.49%	0.40%	2.22%	25.63%	5.98%	0.43%	0.92%	30.02%	5.98%
Total	9,077	44,326	72,379	405	80,026	3,238	59,261	268,712	189,908	28,919	49,885	268,712
	3.38%	16.50%	26.94%	0.15%	29.78%	1.21%	22.05%	100.00%	70.67%	10.76%	18.56%	100.00%
	3.38%	16.50%	26.94%	0.15%	29.78%	1.21%	22.05%	100.00%	70.67%	10.76%	18.56%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	3727	12	83	3	1,883	125	7,213	13,046	73,452
	12.89%	0.04%	0.29%	0.01%	6.51%	0.43%	24.94%	45.11%	27.33%
	28.57%	0.09%	0.64%	0.02%	14.43%	0.96%	55.29%	100.00%	58.68%
	51.86%	37.50%	34.58%	37.50%	44.57%	46.64%	42.53%	45.11%	48.77%
Male	3426	20	157	5	2,342	142	9,514	15,606	76,365
	11.85%	0.07%	0.54%	0.02%	8.10%	0.49%	32.90%	53.96%	28.42%
	21.95%	0.13%	1.01%	0.03%	15.01%	0.91%	60.96%	100.00%	59.91%
	47.68%	62.50%	65.42%	62.50%	55.43%	52.99%	56.10%	53.96%	50.70%
Unknown	33	0	0	0	0	1	233	267	793
	0.11%	0.00%	0.00%	0.00%	0.00%	0.00%	0.81%	0.92%	0.30%
	12.36%	0.00%	0.00%	0.00%	0.00%	0.37%	87.27%	100.00%	4.94%
	0.46%	0.00%	0.00%	0.00%	0.00%	0.37%	1.37%	0.92%	0.53%
TOTAL	7,186	32	240	8	4,225	268	16,960	28,919	150,610
	24.85%	0.11%	0.83%	0.03%	14.61%	0.93%	58.65%	100.00%	56.05%
	24.85%	0.11%	0.83%	0.03%	14.61%	0.93%	58.65%	100.00%	56.05%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 6A

Number of Protocols with Enrollment Data: 122

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	136	714	2,994	16,113	25,805	962	46,724	19,957
	0.16%	**0.83%**	**3.46%**	**18.65%**	**29.86%**	**1.11%**	**54.07%**	**23.10%**
	0.29%	*1.53%*	*6.41%*	*34.49%*	*55.23%*	*2.06%*	*100.00%*	*42.71%*
	45.33%	47.22%	45.56%	87.33%	44.97%	43.89%	54.07%	74.37%
Male	164	798	3,576	2,338	31,563	1,226	39,665	6,876
	0.19%	**0.92%**	**4.14%**	**2.71%**	**36.53%**	**1.42%**	**45.90%**	**7.96%**
	0.41%	*2.01%*	*9.02%*	*5.89%*	*79.57%*	*3.09%*	*100.00%*	*17.34%*
	54.67%	52.78%	54.42%	12.67%	55.00%	55.93%	45.90%	25.62%
Unknown	0	0	1	0	16	4	21	1
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.02%**	**0.00%**	**0.02%**	**0.00%**
	0.00%	*0.00%*	*4.76%*	*0.00%*	*76.19%*	*19.05%*	*100.00%*	*4.76%*
	0.00%	0.00%	0.02%	0.00%	0.03%	0.18%	0.02%	0.00%
Total	300	1,512	6,571	18,451	57,384	2,192	86,410	26,834
	0.35%	**1.75%**	**7.60%**	**21.35%**	**66.41%**	**2.54%**	**100.00%**	**31.05%**
	0.35%	*1.75%*	*7.60%*	*21.35%*	*66.41%*	*2.54%*	*100.00%*	*31.05%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments: Reference Table 4A

Sex/Gender

Excluding sex-specific studies, the number of females (171,908 or 48.41%) exceeded the number of males (167,127 or 47.06%) enrolled in Phase III Extramural Research Protocols.
Excluding sex-specific studies, the number of minority females (93,409 or 52.64%) exceeded the number of minority males (83,241 or 46.91%) enrolled in Phase III Extramural Research Protocols.

Race

Approximately 49.97% (177,444) of participants in Phase III Extramural Research (355,122 total) were classified as U.S. minorities.
Largest identified racial group was White at 66.41% following the 1977 OMB standards.
Largest identified racial group was White at 29.78% following the 1997 OMB standards.
Largest identified racial minority group was Hispanic at 21.35% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 26.94% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.35%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.15%.

Ethnicity

10.76% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 58.65% (2nd largest category is American Indian/ Alaska Native at 24.85%)
Smallest identified racial group was Hawaiian/Pacific Islander at 0.03%.
Of the 28,919 participants, 45.11% were women and 53.96% were men.
21.35% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 7A. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**1,499,945**	**395,722**		**26.38%**
%	**43.39%**	**48.34%**		
Males	**1,915,898**	**421,306**		**21.99%**
%	**55.42%**	**51.47%**		
Unknown	**41,333**	**1,518**		**3.67%**
%	**1.20%**	**0.19%**		
TOTAL	**3,457,176**	**818,546**	**23.68%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**1,552**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **1,103**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	10,730	124,260	55,037	3,467	716,439	9,823	65,286	985,042	888,411	56,223	40,408	985,042
	0.44%	**5.09%**	**2.26%**	**0.14%**	**29.37%**	**0.40%**	**2.68%**	**40.38%**	**36.41%**	**2.30%**	**1.66%**	**40.38%**
	1.09%	*12.61%*	*5.59%*	*0.35%*	*72.73%*	*1.00%*	*6.63%*	*100.00%*	*90.19%*	*5.71%*	*4.10%*	*100.00%*
	49.30%	66.48%	23.21%	86.39%	42.04%	71.83%	23.99%	40.38%	42.59%	54.98%	16.07%	40.38%
Male	11,014	61,936	182,077	546	984,999	3,084	169,715	1,413,371	1,194,236	46,009	173,126	1,413,371
	0.45%	**2.54%**	**7.46%**	**0.02%**	**40.37%**	**0.13%**	6.96%	**57.93%**	**48.95%**	**1.89%**	**7.10%**	**57.93%**
	0.78%	*4.38%*	*12.88%*	*0.04%*	*69.69%*	*0.22%*	12.01%	*100.00%*	*84.50%*	*3.26%*	*12.25%*	*100.00%*
	50.60%	33.14%	76.78%	13.61%	57.80%	22.55%	62.36%	57.93%	57.25%	45.00%	68.84%	57.93%
Unknown	22	706	15	0	2,595	769	37,169	41,276	3289	20	37,967	41,276
	0.00%	**0.03%**	**0.00%**	0.00%	**0.11%**	**0.03%**	***1.52%***	**1.69%**	**0.13%**	**0.00%**	**1.56%**	**1.69%**
	0.05%	*1.71%*	*0.04%*	0.00%	*6.29%*	*1.86%*	*90.05%*	*100.00%*	*7.97%*	*0.05%*	*91.98%*	*100.00%*
	0.10%	0.38%	0.01%	0.00%	0.15%	5.62%	13.66%	1.69%	0.16%	0.02%	15.10%	1.69%
Total	21,766	186,902	237,129	4,013	1,704,033	13,676	272,170	2,439,689	2,085,936	102,252	251,501	2,439,689
	0.89%	**7.66%**	**9.72%**	**0.16%**	**69.85%**	**0.56%**	**11.16%**	**100.00%**	**85.50%**	**4.19%**	**10.31%**	**100.00%**
	0.89%	*7.66%*	*9.72%*	*0.16%*	*69.85%*	*0.56%*	*11.16%*	*100.00%*	*85.50%*	*4.19%*	*10.31%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	1200	14	332	40	25,628	1,875	27,134	56,223	256,079
	1.17%	**0.01%**	**0.32%**	**0.04%**	**25.06%**	**1.83%**	**26.54%**	**54.98%**	**10.50%**
	2.13%	*0.02%*	*0.59%*	*0.07%*	*45.58%*	*3.33%*	*48.26%*	*100.00%*	*26.00%*
	48.98%	43.75%	11.48%	70.18%	44.81%	54.19%	75.03%	54.98%	45.99%
Male	1234	18	2559	17	31,570	1,585	9,026	46,009	299,253
	1.21%	**0.02%**	**2.50%**	**0.02%**	**30.87%**	**1.55%**	**8.83%**	**45.00%**	**12.27%**
	2.68%	*0.04%*	*5.56%*	*0.04%*	*68.62%*	*3.44%*	*19.62%*	*100.00%*	*21.17%*
	50.37%	56.25%	88.52%	29.82%	55.19%	45.81%	24.96%	45.00%	53.74%
Unknown	16	0	0	0	0	0	4	20	1,516
	0.02%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.02%**	**0.06%**
	80.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*20.00%*	*100.00%*	*3.67%*
	0.65%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.02%	0.27%
TOTAL	2,450	32	2,891	57	57,198	3,460	36,164	102,252	556,848
	2.40%	**0.03%**	**2.83%**	**0.06%**	**55.94%**	**3.38%**	**35.37%**	**100.00%**	**22.82%**
	2.40%	*0.03%*	*2.83%*	*0.06%*	*55.94%*	*3.38%*	*35.37%*	*100.00%*	*22.82%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 7A

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

Number of Protocols with Enrollment Data: **449**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	876	19,092	96,523	23,152	369,148	6,112	514,903	139,643
	0.09%	**1.88%**	**9.49%**	**2.28%**	**36.28%**	**0.60%**	**50.61%**	**13.72%**
	0.17%	*3.71%*	*18.75%*	*4.50%*	*71.69%*	*1.19%*	*100.00%*	*27.12%*
	0.00%	51.47%	53.92%	52.74%	49.59%	53.85%	50.61%	53.36%
Male	822	17,999	82,489	20,743	375,273	5,201	502,527	122,053
	0.08%	**1.77%**	**8.11%**	**2.04%**	**36.88%**	**0.51%**	**49.39%**	**12.00%**
	0.16%	*3.58%*	*16.41%*	*4.13%*	*74.68%*	*1.03%*	*100.00%*	*24.29%*
	0.00%	48.53%	46.08%	47.25%	50.41%	45.83%	49.39%	46.64%
Unknown	0	0	1	1	19	36	57	2
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*1.75%*	*1.75%*	*33.33%*	*63.16%*	*100.00%*	*3.51%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.32%	0.01%	0.00%
Total	1,698	37,091	179,013	43,896	744,440	11,349	1,017,487	261,698
	0.17%	**3.65%**	**17.59%**	**4.31%**	**73.16%**	**1.12%**	**100.00%**	**25.72%**
	0.17%	*3.65%*	*17.59%*	*4.31%*	*73.16%*	*1.12%*	*100.00%*	*25.72%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More males (1,915,298 or 55.42%) than females (1,499,945 or 43.39%) were enrolled in aggregate Intramural Research Protocols.
More minority males (421,306 or 51.47%) than females (395,722 or 48.34%) were enrolled in aggregate Intramural Research Protocols.

Race

Approximately 23.68% (818,546) of participants in aggregate Intramural Research (3,457,176 total) were classified as U.S. minorities.
Largest identified racial group was White at 73.16% following the 1977 OMB standards and 69.85% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 17.59% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 9.72% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.17%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.16%.

Ethnicity

4.19% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 55.94% (2nd largest category Unknown/Other at 35.37%).
Smallest identified racial group was Asian at 0.03%.
Of the 102,252 participants, 54.98% were women and 45.00% were men.
4.31% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 8A. Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**1,139,063**	**245,722**		**21.57%**
%	**37.14%**	**37.26%**		
Males	**1,886,711**	**412,304**		**21.85%**
%	**61.51%**	**62.51%**		
Unknown	**41,333**	**1,517**		**3.67%**
%	**1.35%**	**0.23%**		
TOTAL	**3,067,107**	**659,543**	**21.50%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **1,387**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **977**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	9,339	45,617	41,041	3,180	497,405	2,762	34,975	634,319	586,994	14,302	33,023	634,319
	0.45%	**2.21%**	**1.99%**	**0.15%**	**24.14%**	**0.13%**	**1.70%**	**30.79%**	**28.49%**	**0.69%**	**1.60%**	**30.79%**
	1.47%	*7.19%*	*6.47%*	*0.50%*	*78.42%*	*0.44%*	*5.51%*	*100.00%*	*92.54%*	*2.25%*	*5.21%*	*100.00%*
	45.84%	42.20%	18.54%	85.35%	34.11%	41.75%	14.47%	30.79%	33.43%	23.73%	13.53%	30.79%
Male	11,012	61,772	180,356	546	958,276	3,084	169,584	1,384,630	1,165,633	45,947	173,050	1,384,630
	0.53%	**3.00%**	**8.75%**	**0.03%**	**46.51%**	**0.15%**	8.23%	**67.21%**	**56.58%**	**2.23%**	**8.40%**	**67.21%**
	0.80%	*4.46%*	*13.03%*	*0.04%*	*69.21%*	*0.22%*	12.25%	*100.00%*	*84.18%*	*3.32%*	*12.50%*	*100.00%*
	54.05%	57.15%	81.46%	14.65%	65.71%	46.62%	70.15%	67.21%	66.38%	76.24%	70.91%	67.21%
Unknown	22	706	15	0	2,595	769	37,169	41,276	3289	20	37,967	41,276
	0.00%	**0.03%**	**0.00%**	0.00%	**0.13%**	**0.04%**	***1.80%***	**2.00%**	**0.16%**	**0.00%**	**1.84%**	**2.00%**
	0.05%	*1.71%*	*0.04%*	0.00%	*6.29%*	*1.86%*	*90.05%*	*100.00%*	*7.97%*	*0.05%*	*91.98%*	*100.00%*
	0.11%	0.65%	0.01%	0.00%	0.18%	11.63%	15.38%	2.00%	0.19%	0.03%	15.56%	2.00%
Total	20,373	108,095	221,412	3,726	1,458,276	6,615	241,728	2,060,225	1,755,916	60,269	244,040	2,060,225
	0.99%	**5.25%**	**10.75%**	**0.18%**	**70.78%**	**0.32%**	**11.73%**	**100.00%**	**85.23%**	**2.93%**	**11.85%**	**100.00%**
	0.99%	*5.25%*	*10.75%*	*0.18%*	*70.78%*	*0.32%*	*11.73%*	*100.00%*	*85.23%*	*2.93%*	*11.85%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1169	7	272	14	1836	6,424	4,580	14,302	108,355
	1.94%	**0.01%**	**0.45%**	**0.02%**	**3.05%**	**10.66%**	**7.60%**	**23.73%**	**5.26%**
	8.17%	*0.05%*	*1.90%*	*0.10%*	*12.84%*	*44.92%*	*32.02%*	*100.00%*	*17.08%*
	48.33%	28.00%	9.28%	45.16%	53.67%	43.29%	12.51%	23.73%	27.07%
Male	1234	18	2659	17	1585	8,414	32,020	45,947	290,375
	2.05%	**0.03%**	**4.41%**	**0.03%**	**2.63%**	**13.96%**	**53.13%**	**76.24%**	**14.09%**
	2.69%	*0.04%*	*5.79%*	*0.04%*	*3.45%*	*18.31%*	*69.69%*	*100.00%*	*20.97%*
	51.01%	72.00%	90.72%	54.84%	46.33%	56.70%	87.48%	76.24%	72.55%
Unknown	16	0	0	0	0	1	3	20	1,515
	0.03%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.03%**	**0.07%**
	80.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*5.00%*	*15.00%*	*100.00%*	*3.67%*
	0.66%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.03%	0.38%
TOTAL	2,419	25	2,931	31	3,421	14,839	36,603	60,269	400,245
	4.01%	**0.04%**	**4.86%**	**0.05%**	**5.68%**	**24.62%**	**60.73%**	**100.00%**	**19.43%**
	4.01%	*0.04%*	*4.86%*	*0.05%*	*5.68%*	*24.62%*	*60.73%*	*100.00%*	*19.43%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 8A.

Number of Protocols with Enrollment Data: **410**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	866	18,820	94,841	22,840	361,664	5,713	504,744	137,367
	0.09%	**1.87%**	**9.42%**	**2.27%**	**35.92%**	**0.57%**	**50.13%**	**13.64%**
	0.17%	*3.73%*	*18.79%*	*4.53%*	*71.65%*	*1.13%*	*100.00%*	*27.22%*
	51.30%	51.12%	53.51%	52.44%	49.10%	52.23%	50.13%	52.98%
Male	822	17,993	82,399	20,715	374,962	5,190	502,081	121,929
	0.08%	**1.79%**	**8.18%**	**2.06%**	**37.24%**	**0.52%**	**49.86%**	**12.11%**
	0.16%	*3.58%*	*16.41%*	*4.13%*	*74.68%*	*1.03%*	*100.00%*	*24.28%*
	48.70%	48.88%	46.49%	47.56%	50.90%	47.44%	49.86%	47.02%
Unknown	0	0	1	1	19	36	57	2
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*1.75%*	*1.75%*	*33.33%*	*63.16%*	*100.00%*	*3.51%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.33%	0.01%	0.00%
Total	1,688	36,813	177,241	43,556	736,645	10,939	1,006,882	259,298
	0.17%	**3.66%**	**17.60%**	**4.33%**	**73.16%**	**1.09%**	**100.00%**	**25.75%**
	0.17%	*3.66%*	*17.60%*	*4.33%*	*73.16%*	*1.09%*	*100.00%*	*25.75%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

Excluding sex-specific studies, the number of males (1,886,711 or 61.51%) exceeded the number of females (1,139,063 or 37.14%) enrolled in Intramural Research Protocols.
Excluding sex-specific studies, the number of minority males (412,304 or 62.51%) exceeded the number of minority females (245,722 or 37.26%) enrolled in Intramural Research Protocols.

Race

Approximately 21.50% (659,543) of participants in aggregate Intramural Research (3,067,107 total) were classified as U.S. minorities.
Largest identified racial group was White at 73.16% following the 1977 OMB standards and 70.78% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 17.60% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 10.75% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.17%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.18%.

Ethnicity

2.93% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 60.73% (2nd largest category was More Than One Race at 24.62%)
Smallest identified racial group was Asian at 0.04%.
Of the 60,269 participants, 76.24% were men and 23.73% were women.
4.33% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 9A. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	22,959	9,212		40.12%
%	52.81%	77.58%		
Males	20,511	2,662		12.98%
%	47.18%	22.42%		
Unknown	2	0		0.00%
%	0.00%	0.00%		
TOTAL	43,472	11,874	27.31%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 36

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 25

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	11	95	544	72	5,366	266	8,523	14,877	6,016	7,307	1,554	14,877
	0.05%	0.45%	2.57%	0.34%	25.31%	1.25%	40.21%	70.18%	28.38%	34.47%	7.33%	70.18%
	0.07%	0.64%	3.66%	0.48%	36.07%	1.79%	57.29%	100.00%	40.44%	49.12%	10.45%	100.00%
	47.83%	45.89%	64.84%	100.00%	56.86%	55.53%	84.06%	70.18%	57.27%	96.78%	49.46%	70.18%
Male	12	112	295	0	4,072	213	1,614	6,318	4,489	243	1,586	6,318
	0.06%	0.53%	1.39%	0.00%	19.21%	1.00%	7.61%	29.81%	21.18%	1.15%	7.48%	29.81%
	0.19%	1.77%	4.67%	0.00%	64.45%	3.37%	25.55%	100.00%	71.05%	3.85%	25.10%	100.00%
	52.17%	54.11%	35.16%	0.00%	43.14%	44.47%	15.92%	29.81%	42.73%	3.22%	50.48%	29.81%
Unknown	0	0	0	0	0	0	2	2	0	0	2	2
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.01%	0.01%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.00%	0.00%	0.06%	0.01%
Total	23	207	839	72	9,438	479	10,139	21,197	10,505	7,550	3,142	21,197
	0.11%	0.98%	3.96%	0.34%	44.53%	2.26%	47.83%	100.00%	49.56%	35.62%	14.82%	100.00%
	0.11%	0.98%	3.96%	0.34%	44.53%	2.26%	47.83%	100.00%	49.56%	35.62%	14.82%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1	0	0	0	2	1	7,303	7,307	8,293
	0.01%	0.00%	0.00%	0.00%	0.03%	0.01%	96.73%	96.78%	39.12%
	0.01%	0.00%	0.00%	0.00%	0.03%	0.01%	99.95%	100.00%	55.74%
	100.00%	0.00%	0.00%	0.00%	66.67%	100.00%	96.79%	96.78%	90.46%
Male	0	0	0	0	1	0	242	243	875
	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	3.21%	3.22%	4.13%
	0.00%	0.00%	0.00%	0.00%	0.41%	0.00%	99.59%	100.00%	13.85%
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	3.21%	3.22%	9.54%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	1	0	0	0	3	1	7,545	7,550	9,168
	0.01%	0.00%	0.00%	0.00%	0.04%	0.01%	99.93%	100.00%	43.25%
	0.01%	0.00%	0.00%	0.00%	0.04%	0.01%	99.93%	100.00%	43.25%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%

Table 9A

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

Number of Protocols with Enrollment Data: **11**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
	6	169	570	174	7,132	31	8,082	919
	0.03%	**0.76%**	**2.56%**	**0.78%**	**32.02%**	**0.14%**	**36.28%**	**4.13%**
	0.07%	*2.09%*	*7.05%*	*2.15%*	*88.25%*	*0.38%*	*100.00%*	*11.37%*
	0.00%	37.81%	33.18%	33.79%	36.62%	32.63%	36.28%	33.96%
Male	20	278	1,148	341	12,342	64	14,193	1,787
	0.09%	**1.25%**	**5.15%**	**1.53%**	**55.41%**	**0.29%**	**63.72%**	**8.02%**
	0.14%	*1.96%*	*8.09%*	*2.40%*	*86.96%*	*0.45%*	*100.00%*	*12.59%*
	0.00%	62.19%	66.82%	66.21%	63.38%	67.37%	63.72%	66.04%
Unknown	0	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	26	447	1,718	515	19,474	95	22,275	2,706
	0.12%	**2.01%**	**7.71%**	**2.31%**	**87.43%**	**0.43%**	**100.00%**	**12.15%**
	0.12%	*2.01%*	*7.71%*	*2.31%*	*87.43%*	*0.43%*	*100.00%*	*12.15%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (22,959 or 52.81%) than males (20,511 or 47.18%) were enrolled in aggregate Intramural Phase III Research Protocols.
More minority females (9,212 or 77.58%) than males (2,662 or 22.42%) are enrolled in aggregate Intramural Phase III Research Protocols.
Compared to FY2006, minority female enrollment decreased by 1.16% and minority male enrollment increased by 1.15%.

Race

Approximately 27.31% (11,874) of participants in aggregate Intramural Phase III Research (43,472 total) were classified as U.S. minorities.
Largest identified racial group was White at 87.43% following the 1977 OMB standards and 44.53% following the 1997 OMB standards.
This is a significant change from FY2006 when, according to the 1977 OMB standards, Asian/Pacific Islander was the largest identified racial group at 78.7%.
Largest identified racial minority group was Black or African American at 7.71% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 3.96% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.11%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.12%.

Ethnicity

35.62% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 99.93% (2nd largest category is White at 0.04%).
Asian, Black or African American and Hawaiian/Pacific Islander all had 0.0%.
Of the 7,550 participants, 96.78% were women and 3.22% were men.
2.31% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 10A. Aggregate Enrollment Data for Intramural Phase III Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	15,928	2,182		13.70%
%	43.71%	45.05%		
Males	20,511	2,662		12.98%
%	56.29%	54.95%		
Unknown	2	0		0.00%
%	0.01%	0.00%		
TOTAL	36,441	4,844	13.29%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	31

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 20

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	11	95	539	56	5,365	266	1,514	7,846	6,010	298	1,538	7,846
	0.08%	**0.67%**	**3.80%**	**0.40%**	**37.87%**	**1.88%**	**10.69%**	**55.39%**	**42.43%**	**2.10%**	**10.86%**	**55.39%**
	0.14%	*1.21%*	*6.87%*	*0.71%*	*68.38%*	*3.39%*	*19.30%*	*100.00%*	*76.60%*	*3.80%*	*19.60%*	*100.00%*
	47.83%	45.89%	64.63%	100.00%	56.85%	55.53%	48.37%	55.39%	57.24%	55.08%	49.20%	55.39%
Male	12	112	295	0	4,072	213	1,614	6,318	4,489	243	1,586	6,318
	0.08%	**0.79%**	**2.08%**	**0.00%**	**28.74%**	**1.50%**	11.39%	**44.60%**	**31.69%**	**1.72%**	**11.20%**	**44.60%**
	0.19%	*1.77%*	*4.67%*	*0.00%*	*64.45%*	*3.37%*	25.55%	*100.00%*	*71.05%*	*3.85%*	*25.10%*	*100.00%*
	52.17%	54.11%	35.37%	0.00%	43.15%	44.47%	51.57%	44.60%	42.76%	44.92%	50.74%	44.60%
Unknown	0	0	0	0	0	0	2	2	0	0	2	2
	0.00%	**0.00%**	**0.00%**	0.00%	**0.00%**	**0.00%**	***0.01%***	**0.01%**	**0.00%**	**0.00%**	**0.01%**	**0.01%**
	0.00%	*0.00%*	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.06%	0.01%	0.00%	0.00%	0.06%	0.01%
Total	23	207	834	56	9,437	479	3,130	14,166	10,499	541	3,126	14,166
	0.16%	**1.46%**	**5.89%**	**0.40%**	**66.62%**	**3.38%**	**22.10%**	**100.00%**	**74.11%**	**3.82%**	**22.07%**	**100.00%**
	0.16%	*1.46%*	*5.89%*	*0.40%*	*66.62%*	*3.38%*	*22.10%*	*100.00%*	*74.11%*	*3.82%*	*22.07%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1	0	0	0	2	1	294	298	1,263
	0.18%	**0.00%**	**0.00%**	**0.00%**	**0.37%**	**0.18%**	**54.34%**	**55.08%**	**8.92%**
	0.34%	*0.00%*	*0.00%*	*0.00%*	*0.67%*	*0.34%*	*98.66%*	*100.00%*	*16.10%*
	100.00%	0.00%	0.00%	0.00%	66.67%	100.00%	54.85%	55.08%	59.07%
Male	0	0	0	0	1	0	242	243	875
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.18%**	**0.00%**	**44.73%**	**44.92%**	**6.18%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.41%*	*0.00%*	*99.59%*	*100.00%*	*13.85%*
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	45.15%	44.92%	40.93%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	1	0	0	0	3	1	536	541	2,138
	0.18%	**0.00%**	**0.00%**	**0.00%**	**0.55%**	**0.18%**	**99.08%**	**100.00%**	**15.09%**
	0.18%	*0.00%*	*0.00%*	*0.00%*	*0.55%*	*0.18%*	*99.08%*	*100.00%*	*15.09%*
	100.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 10A.

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

Number of Protocols with Enrollment Data: **11**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	6	169	570	174	7,132	31	8,082	919
	0.03%	**0.76%**	**2.56%**	**0.78%**	**32.02%**	**0.14%**	**36.28%**	**4.13%**
	0.07%	*2.09%*	*7.05%*	*2.15%*	*88.25%*	*0.38%*	*100.00%*	*11.37%*
	23.08%	37.81%	33.18%	33.79%	36.62%	32.63%	36.28%	33.96%
Male	20	278	1,148	341	12,342	64	14,193	1,787
	0.09%	**1.25%**	**5.15%**	**1.53%**	**55.41%**	**0.29%**	**63.72%**	**8.02%**
	0.14%	*1.96%*	*8.09%*	*2.40%*	*86.96%*	*0.45%*	*100.00%*	*12.59%*
	76.92%	62.19%	66.82%	66.21%	63.38%	67.37%	63.72%	66.04%
Unknown	0	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	26	447	1,718	515	19,474	95	22,275	2,706
	0.12%	**2.01%**	**7.71%**	**2.31%**	**87.43%**	**0.43%**	**100.00%**	**12.15%**
	0.12%	*2.01%*	*7.71%*	*2.31%*	*87.43%*	*0.43%*	*100.00%*	*12.15%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

There were 36 Phase III Intramural Research Protocols of which 5 (13.89%) were female-only protocols and 0 (0.0%) were male-only protocols.
Excluding sex-specific studies, the number of males (20,511 or 56.29%) exceeded the number of females (15,928 or 43.71%) enrolled in Phase III Intramural Research Protocols.
Excluding sex-specific studies, the number of minority males (2,662 or 54.95%) exceeded the number of minority females (2,182 or 45.05%) enrolled in Phase III Intramural Research Protocols.

Race

Approximately 13.29% (4,844) of participants in aggregate Phase III Intramural Research (36,441 total) were classified as U.S. minorities.
Largest identified racial group was White at 87.43% following the 1977 OMB standards and 66.62% following the 1997 OMB Standards
Largest identified racial minority group was Black or African American at 7.71% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 5.89% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.12%.
According to the 1997 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.16%.

Ethnicity

3.82% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 99.08% (2nd largest category was White at 0.55%)
Smallest identified racial groups were Hawaiian/Pacific Islander, Asian and Black or African American, all at 0.00%.
Of the 541 participants, 55.08% were women and 44.92% were men.
2.31% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 11A. DOMESTIC Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**9,397,957**	**2,534,431**		**26.97%**
%	**58.08%**	**59.16%**		
Males	**6,389,817**	**1,736,038**		**27.17%**
%	**39.49%**	**40.53%**		
Unknown	**392,814**	**13,269**		**3.38%**
%	**2.43%**	**0.31%**		
TOTAL	**16,180,588**	**4,283,738**	**26.47%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**10,463**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 9,371

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	88,458	615,470	897,939	28,356	6,004,328	165,960	808,187	8,608,698	7,198,571	628,417	781,710	8,608,698
	0.60%	**4.20%**	**6.13%**	**0.19%**	**40.96%**	**1.13%**	**5.51%**	**58.72%**	**49.11%**	**4.29%**	**5.33%**	**58.72%**
	1.03%	*7.15%*	*10.43%*	*0.33%*	*69.75%*	*1.93%*	*9.39%*	*100.00%*	*83.62%*	*7.30%*	*9.08%*	*100.00%*
	68.13%	68.97%	52.22%	60.89%	59.87%	61.47%	51.41%	58.72%	60.03%	62.70%	46.93%	58.72%
Male	40,950	275,267	816,588	18,075	4,004,182	101,442	409,911	5,666,415	4,770,679	371,472	524,264	5,666,415
	0.28%	**1.88%**	**5.57%**	**0.12%**	**27.31%**	**0.69%**	2.80%	**38.65%**	**32.54%**	**2.53%**	**3.58%**	**38.65%**
	0.72%	*4.86%*	*14.41%*	*0.32%*	*70.67%*	*1.79%*	7.23%	*100.00%*	*84.19%*	*6.56%*	*9.25%*	*100.00%*
	31.54%	30.85%	47.49%	38.81%	39.93%	37.57%	26.08%	38.65%	39.78%	37.06%	31.47%	38.65%
Unknown	422	1,673	5,104	138	20,482	2,603	353,934	384,356	22,138	2,413	359,805	384,356
	0.00%	**0.01%**	**0.03%**	0.00%	**0.14%**	**0.02%**	***2.41%***	**2.62%**	**0.15%**	**0.02%**	**2.45%**	**2.62%**
	0.11%	*0.44%*	*1.33%*	0.04%	*5.33%*	*0.68%*	*92.08%*	*100.00%*	*5.76%*	*0.63%*	*93.61%*	*100.00%*
	0.33%	0.19%	0.30%	0.30%	0.20%	0.96%	22.51%	2.62%	0.18%	0.24%	21.60%	2.62%
Total	129,830	892,410	1,719,631	46,569	10,028,992	270,005	1,572,032	14,659,469	11,991,388	1,002,302	1,665,779	14,659,469
	0.89%	**6.09%**	**11.73%**	**0.32%**	**68.41%**	**1.84%**	**10.72%**	**100.00%**	**81.80%**	**6.84%**	**11.36%**	**100.00%**
	0.89%	*6.09%*	*11.73%*	*0.32%*	*68.41%*	*1.84%*	*10.72%*	*100.00%*	*81.80%*	*6.84%*	*11.36%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	11,781	5,303	15,648	2131	329,924	54,739	208,891	628,417	2,334,998
	1.18%	**0.53%**	**1.56%**	**0.21%**	**32.92%**	**5.46%**	**20.84%**	**62.70%**	**15.93%**
	1.87%	*0.84%*	*2.49%*	*0.34%*	*52.50%*	*8.71%*	*33.24%*	*100.00%*	*27.12%*
	56.28%	77.13%	55.73%	66.61%	66.90%	57.79%	58.79%	62.70%	59.77%
Male	9,112	1,536	12,377	1054	162620	39,644	145,129	371,472	1,560,071
	0.91%	**0.15%**	**1.23%**	**0.11%**	**16.22%**	**3.96%**	**14.48%**	**37.06%**	**10.64%**
	2.45%	*0.41%*	*3.33%*	*0.28%*	*43.78%*	*10.67%*	*39.07%*	*100.00%*	*27.53%*
	43.53%	22.34%	44.08%	32.95%	32.97%	41.86%	40.85%	37.06%	39.93%
Unknown	39	36	53	14	652	334	1,285	2,413	11,877
	0.00%	**0.00%**	**0.01%**	**0.00%**	**0.07%**	**0.03%**	**0.13%**	**0.24%**	**0.08%**
	1.62%	*1.49%*	*2.20%*	*0.58%*	*27.02%*	*13.84%*	*53.25%*	*100.00%*	*3.09%*
	0.19%	0.52%	0.19%	0.44%	0.13%	0.35%	0.36%	0.24%	0.30%
TOTAL	20,932	6,875	28,078	3,199	493,196	94,717	355,305	1,002,302	3,906,946
	2.09%	**0.69%**	**2.80%**	**0.32%**	**49.21%**	**9.45%**	**35.45%**	**100.00%**	**26.65%**
	2.09%	*0.69%*	*2.80%*	*0.32%*	*49.21%*	*9.45%*	*35.45%*	*100.00%*	*26.65%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 11 A

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

Number of Protocols with Enrollment Data: **1,092**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	2,680	26,935	127,508	42,310	566,576	23,250	789,259	199,433
	0.18%	**1.77%**	**8.38%**	**2.78%**	**37.25%**	**1.53%**	**51.89%**	**13.11%**
	0.34%	*3.41%*	*16.16%*	*5.36%*	*71.79%*	*2.95%*	*100.00%*	*25.27%*
	0.00%	52.06%	53.57%	51.80%	51.71%	47.81%	51.89%	52.93%
Male	2,549	24,637	109,916	38,865	527,390	20,045	723,402	175,967
	0.17%	**1.62%**	**7.23%**	**2.56%**	**34.67%**	**1.32%**	**47.56%**	**11.57%**
	0.35%	*3.41%*	*15.19%*	*5.37%*	*72.90%*	*2.77%*	*100.00%*	*24.32%*
	0.00%	47.62%	46.18%	47.58%	48.13%	41.22%	47.56%	46.70%
Unknown	143	168	579	502	1,736	5,330	8,458	1392
	0.009%	**0.01%**	**0.04%**	**0.03%**	**0.11%**	**0.35%**	**0.56%**	**0.09%**
	1.69%	*1.99%*	*6.85%*	*5.94%*	*20.52%*	*63.02%*	*100.00%*	*16.46%*
	0.00%	0.32%	0.24%	0.61%	0.16%	10.96%	0.56%	0.37%
Total	5,372	51,740	238,003	81,677	1,095,702	48,625	1,521,119	376,792
	0.35%	**3.40%**	**15.65%**	**5.37%**	**72.03%**	**3.20%**	**100.00%**	**24.77%**
	0.35%	*3.40%*	*15.65%*	*5.37%*	*72.03%*	*3.20%*	*100.00%*	*24.77%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (9,397,957 or 58.08%) than males (6,389,817 or 39.49%) were enrolled in aggregate Domestic Extramural and Intramural Research Protocols.
More minority females (2,534,431 or 59.16%) than males (1,736,038 or 40.53%) were enrolled in aggregate Domestic Extramural and Intramural Research Protocols.

Race

Approximately 26.47% (4,283,738) of participants in aggregate Domestic Extramural and Intramural Research (16,180,602 total) were classified as U.S. minorities.
Largest identified racial group was White at 72.03% following the 1977 OMB standards and 70.60% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 15.65% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 11.73% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.32%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.35%.

Ethnicity

6.84% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards (Decrease of 0.97% over FY2006).
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 49.21% (2nd largest category was Unknown/Other at 35.45%).
Smallest identified racial group was Asian at 0.69%.
Of the 1,002,302 participants, 62.70% were women and 37.06% were men.
5.37% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 12A. DOMESTIC Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	8,130,874	2,273,947		27.97%
%	62.16%	62.27%		
Males	4,594,511	1,365,350		29.72%
%	35.13%	37.39%		
Unknown	354,966	12,425		3.50%
%	2.71%	0.34%		
TOTAL	13,080,351	3,651,722	27.92%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 8,906

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 8,272

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	77,732	601,048	845,597	24,891	5,377,482	157,995	771773	7,856,518	6,506,712	595,980	753,826	7,856,518
	0.62%	4.78%	6.72%	0.20%	42.76%	1.26%	6.14%	62.47%	51.74%	4.74%	5.99%	62.47%
	0.99%	7.65%	10.76%	0.32%	68.45%	2.01%	9.82%	100.00%	82.82%	7.59%	9.59%	100.00%
	71.93%	69.93%	56.79%	58.49%	63.43%	60.84%	57.57%	62.47%	63.75%	64.20%	52.28%	62.47%
Male	29,936	256,822	638,263	17,529	3,079,485	99,879	251722	4,373,636	3,677,924	329,885	365,827	4,373,636
	0.24%	2.04%	5.07%	0.14%	24.49%	0.79%	2.00%	34.78%	29.24%	2.62%	2.91%	34.78%
	0.68%	5.87%	14.59%	0.40%	70.41%	2.28%	5.76%	100.00%	84.09%	7.54%	8.36%	100.00%
	27.70%	29.88%	42.87%	41.19%	36.33%	38.46%	18.78%	34.78%	36.03%	35.54%	25.37%	34.78%
Unknown	400	1,641	5,089	138	20,372	1,834	317,091	346,565	22,008	2,409	322,148	346,565
	0.00%	0.01%	0.04%	0.00%	0.16%	0.01%	2.52%	2.76%	0.17%	0.02%	2.56%	2.76%
	0.12%	0.47%	1.47%	0.04%	5.88%	0.53%	91.50%	100.00%	6.35%	0.70%	92.95%	100.00%
	0.37%	0.19%	0.34%	0.32%	0.24%	0.71%	23.65%	2.76%	0.22%	0.26%	22.34%	2.76%
Total	108,068	859,511	1,488,949	42,558	8,477,339	259,708	1,340,586	12,576,719	10,206,644	928,274	1,441,801	12,576,719
	0.86%	6.83%	11.84%	0.34%	67.41%	2.06%	10.66%	100.00%	81.16%	7.38%	11.46%	100.00%
	0.86%	6.83%	11.84%	0.34%	67.41%	2.06%	10.66%	100.00%	81.16%	7.38%	11.46%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	11,727	5,289	15,391	2092	305,819	54,587	201,075	595,980	2,214,157
	1.26%	0.57%	1.66%	0.23%	32.94%	5.88%	21.66%	64.20%	17.61%
	1.97%	0.89%	2.58%	0.35%	51.31%	9.16%	33.74%	100.00%	28.18%
	56.25%	77.29%	61.06%	66.56%	69.69%	57.82%	59.32%	64.20%	62.61%
Male	9,082	1,518	9,761	1037	132380	39,480	136,627	329,885	1,311,436
	0.98%	0.16%	1.05%	0.11%	14.26%	4.25%	14.72%	35.54%	10.43%
	2.75%	0.46%	2.96%	0.31%	40.13%	11.97%	41.42%	100.00%	29.99%
	43.56%	22.18%	38.73%	32.99%	30.17%	41.82%	40.30%	35.54%	37.08%
Unknown	39	36	53	14	652	334	1,281	2,409	11,035
	0.00%	0.00%	0.01%	0.00%	0.07%	0.04%	0.14%	0.26%	0.09%
	1.62%	1.49%	2.20%	0.58%	27.07%	13.86%	53.18%	100.00%	3.18%
	0.19%	0.53%	0.21%	0.45%	0.15%	0.35%	0.38%	0.26%	0.31%
TOTAL	20,848	6,843	25,205	3,143	438,851	94,401	338,983	928,274	3,536,628
	2.25%	0.74%	2.72%	0.34%	47.28%	10.17%	36.52%	100.00%	28.12%
	2.25%	0.74%	2.72%	0.34%	47.28%	10.17%	36.52%	100.00%	28.12%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 12A

Number of Protocols with Enrollment Data: **634**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	1,804	7,843	30,985	19,158	197,428	17,138	274,356	59,790
	0.36%	**1.56%**	**6.15%**	**3.80%**	**39.20%**	**3.40%**	**54.48%**	**11.87%**
	0.66%	*2.86%*	*11.29%*	*6.98%*	*71.96%*	*6.25%*	*100.00%*	*21.79%*
	49.10%	53.54%	52.53%	50.71%	56.21%	45.98%	54.48%	51.95%
Male	1,727	6,638	27,427	18,122	152,117	14,844	220,875	53,914
	0.34%	**1.32%**	**5.45%**	**3.60%**	**30.20%**	**2.95%**	**43.86%**	**10.71%**
	0.78%	*3.01%*	*12.42%*	*8.20%*	*68.87%*	*6.72%*	*100.00%*	*24.41%*
	47.01%	45.31%	46.49%	47.97%	43.31%	39.82%	43.86%	46.84%
Unknown	143	168	578	501	1,717	5,294	8,401	1,390
	0.028%	**0.03%**	**0.11%**	**0.10%**	**0.34%**	**1.05%**	**1.67%**	**0.28%**
	1.70%	*2.00%*	*6.88%*	*5.96%*	*20.44%*	*63.02%*	*100.00%*	*16.55%*
	3.89%	1.15%	0.98%	1.33%	0.49%	14.20%	1.67%	1.21%
Total	3,674	14,649	58,990	37,781	351,262	37,276	503,632	115,094
	0.73%	**2.91%**	**11.71%**	**7.50%**	**69.75%**	**7.40%**	**100.00%**	**22.85%**
	0.73%	*2.91%*	*11.71%*	*7.50%*	*69.75%*	*7.40%*	*100.00%*	*22.85%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (8,130,874 or 62.16%) than males (4,594,511 or 35.13%) were enrolled in aggregate Domestic Extramural Research Protocols.
More minority females (2,273,947 or 62.27%) than males (1,365,350 or 37.39%) were enrolled in aggregate Domestic Extramural Research Protocols.

Race

Approximately 27.92% (3,651,722) of participants in aggregate Domestic Extramural Research (13,080,351 total) were classified as U.S. minorities.
Largest identified racial group was White at 69.75% following the 1977 OMB standards and 67.41% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 11.71% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 11.84% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.34%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.73%.

Ethnicity

7.38% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 47.28% (2nd largest category was Unknown/Other at 36.52%).
Smallest identified racial group was Hawaiian/Pacific Islander at 0.34%.
Of the 928,274 participants, 64.20% were women and 35.54% were men.
7.50% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 13A. DOMESTIC Aggregate Enrollment Data for Intramural Research Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**1,267,083**	**260,484**		**20.56%**
%	**40.87%**	**41.21%**		
Males	**1,795,306**	**370,688**		**20.65%**
%	**57.91%**	**58.65%**		
Unknown	**37,848**	**844**		**2.23%**
%	**1.22%**	**0.13%**		
TOTAL	**3,100,237**	**632,016**	**20.39%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**1,481**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **1,032**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	10,726	14,422	52,342	3,465	626,846	7,965	36,414	752,180	691,859	32,437	27,884	752,180
	0.51%	**0.69%**	**2.51%**	**0.17%**	**30.10%**	**0.38%**	**1.75%**	**36.11%**	**33.22%**	**1.56%**	**1.34%**	**36.11%**
	1.43%	*1.92%*	*6.96%*	*0.46%*	*83.34%*	*1.06%*	*4.84%*	*100.00%*	*91.98%*	*4.31%*	*3.71%*	*100.00%*
	49.29%	43.84%	22.69%	86.39%	40.40%	77.35%	15.73%	36.11%	38.77%	43.82%	12.45%	36.11%
Male	11,014	18,445	178,325	546	924,697	1,563	158,189	1,292,779	1,092,755	41,587	158,437	1,292,779
	0.53%	**0.89%**	**8.56%**	**0.03%**	**44.40%**	**0.08%**	7.60%	**62.07%**	**52.47%**	**2.00%**	**7.61%**	**62.07%**
	0.85%	*1.43%*	*13.79%*	*0.04%*	*71.53%*	*0.12%*	12.24%	*100.00%*	*84.53%*	*3.22%*	*12.26%*	*100.00%*
	50.61%	56.07%	77.30%	13.61%	59.59%	15.18%	68.35%	62.07%	61.23%	56.18%	70.74%	62.07%
Unknown	22	32	15	0	110	769	36,843	37,791	130	4	37,657	37,791
	0.00%	**0.00%**	**0.00%**	0.00%	**0.01%**	**0.04%**	*1.77%*	**1.81%**	**0.01%**	**0.00%**	**1.81%**	**1.81%**
	0.06%	*0.08%*	*0.04%*	0.00%	*0.29%*	*2.03%*	*97.49%*	*100.00%*	*0.34%*	*0.01%*	*99.65%*	*100.00%*
	0.10%	0.10%	0.01%	0.00%	0.01%	7.47%	15.92%	1.81%	0.01%	0.01%	16.81%	1.81%
Total	21,762	32,899	230,682	4,011	1,551,653	10,297	231,446	2,082,750	1,784,744	74,028	223,978	2,082,750
	1.04%	**1.58%**	**11.08%**	**0.19%**	**74.50%**	**0.49%**	**11.11%**	**100.00%**	**85.69%**	**3.55%**	**10.75%**	**100.00%**
	1.04%	*1.58%*	*11.08%*	*0.19%*	*74.50%*	*0.49%*	*11.11%*	*100.00%*	*85.69%*	*3.55%*	*10.75%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	54	14	257	39	24,107	152	7,814	32,437	120,841
	0.07%	**0.02%**	**0.35%**	**0.05%**	**32.56%**	**0.21%**	**10.56%**	**43.82%**	**5.80%**
	0.17%	*0.04%*	*0.79%*	*0.12%*	*74.32%*	*0.47%*	*24.09%*	*100.00%*	*16.07%*
	64.29%	43.75%	8.95%	69.64%	44.36%	48.10%	47.89%	43.82%	32.63%
Male	30	18	2616	17	30,243	164	8,499	41,587	248,635
	0.04%	**0.02%**	**3.53%**	**0.02%**	**40.85%**	**0.22%**	**11.48%**	**56.18%**	**11.94%**
	0.07%	*0.04%*	*6.29%*	*0.04%*	*72.72%*	*0.39%*	*20.44%*	*100.00%*	*19.23%*
	35.71%	56.25%	91.05%	30.36%	55.64%	51.90%	52.09%	56.18%	67.14%
Unknown	0	0	0	0	0	0	4	4	842
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.01%**	**0.04%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*2.23%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.23%
TOTAL	84	32	2,873	56	54,350	316	16,317	74,028	370,318
	0.11%	**0.04%**	**3.88%**	**0.08%**	**73.42%**	**0.43%**	**22.04%**	**100.00%**	**17.78%**
	0.11%	*0.04%*	*3.88%*	*0.08%*	*73.42%*	*0.43%*	*22.04%*	*100.00%*	*17.78%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 13A

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

Number of Protocols with Enrollment Data: **449**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	876	19,092	96,523	23,152	369,148	6,112	514,903	139,643
	0.09%	**1.88%**	**9.49%**	**2.28%**	**36.28%**	**0.60%**	**50.61%**	**13.72%**
	0.17%	*3.71%*	*18.75%*	*4.50%*	*71.69%*	*1.19%*	*100.00%*	*27.12%*
	51.59%	51.47%	53.92%	52.74%	49.59%	53.85%	50.61%	53.36%
Male	822	17,999	82,489	20,743	375,273	5,201	502,527	122,053
	0.08%	**1.77%**	**8.11%**	**2.04%**	**36.88%**	**0.51%**	**49.39%**	**12.00%**
	0.16%	*3.58%*	*16.41%*	*4.13%*	*74.68%*	*1.03%*	*100.00%*	*24.29%*
	48.41%	48.53%	46.08%	47.25%	50.41%	45.83%	49.39%	46.64%
Unknown	0	0	1	1	19	36	57	2
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*1.75%*	*1.75%*	*33.33%*	*63.16%*	*100.00%*	*3.51%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.32%	0.01%	0.00%
Total	1,698	37,091	179,013	43,896	744,440	11,349	1,017,487	261,698
	0.17%	**3.65%**	**17.59%**	**4.31%**	**73.16%**	**1.12%**	**100.00%**	**25.72%**
	0.17%	*3.65%*	*17.59%*	*4.31%*	*73.16%*	*1.12%*	*100.00%*	*25.72%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender

More males (1,795,306 or 57.91%) than females (1,267,083 or 40.87%) were enrolled in aggregate Domestic Intramural Research Protocols.
More minority males (370,688 or 58.65%) than females (260,484 or 41.21%) were enrolled in aggregate Domestic Intramural Research Protocols.

Race

Approximately 20.39% (632,016) of participants in aggregate Domestic Intramural Research (3,100,237 total) were classified as U.S. minorities.
Largest identified racial group was White at 73.16% following the 1977 OMB standards and 74.50% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 17.59% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 11.08% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.19%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.17%.

Ethnicity

3.55% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 73.42% (2nd largest category was Unknown/Other at 22.04%).
Smallest identified racial group was Asian at 0.04%.
Of the 74,028 participants, 43.82% were women and 56.18% were men.
This is a significant change from FY2006 when 72.5% were women (decrease of 28.68%) and 27.5% were men (increase of 28.68%).
4.31% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 14A. DOMESTIC Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**213,778**	**47,367**		**22.16%**
%	**54.13%**	**56.64%**		
Males	**164,887**	**36,032**		**21.85%**
%	**41.75%**	**43.08%**		
Unknown	**16,271**	**235**		**1.44%**
%	**4.12%**	**0.28%**		
TOTAL	**394,936**	**83,634**	**21.18%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**577**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 384

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	1,411	1,737	13,859	262	63,838	1,799	24,098	107,004	73,489	12,367	21,148	107,004
	0.67%	**0.83%**	**6.62%**	**0.13%**	**30.51%**	**0.86%**	**11.52%**	**51.14%**	**35.12%**	**5.91%**	**10.11%**	**51.14%**
	1.32%	*1.62%*	*12.95%*	*0.24%*	*59.66%*	*1.68%*	*22.52%*	*100.00%*	*68.68%*	*11.56%*	*19.76%*	*100.00%*
	61.59%	42.50%	67.75%	54.47%	52.91%	51.47%	41.72%	51.14%	53.98%	58.71%	40.65%	51.14%
Male	866	2,331	6,570	217	56,492	1,666	17,830	85,972	62,253	8,554	15,165	85,972
	0.41%	**1.11%**	**3.14%**	**0.10%**	**27.00%**	**0.80%**	8.52%	**41.09%**	**29.75%**	**4.09%**	**7.25%**	**41.09%**
	1.01%	*2.71%*	*7.64%*	*0.25%*	*65.71%*	*1.94%*	20.74%	*100.00%*	*72.41%*	*9.95%*	*17.64%*	*100.00%*
	37.80%	57.03%	32.12%	45.11%	46.82%	47.67%	30.86%	41.09%	45.73%	40.61%	29.15%	41.09%
Unknown	14	19	28	2	317	30	15,840	16,250	390	143	15,717	16,250
	0.01%	**0.01%**	**0.01%**	0.00%	**0.15%**	**0.01%**	*7.57%*	**7.77%**	**0.19%**	**0.07%**	**7.51%**	**7.77%**
	0.09%	*0.12%*	*0.17%*	0.01%	*1.95%*	*0.18%*	97.48%	*100.00%*	*2.40%*	*0.88%*	*96.72%*	*100.00%*
	0.61%	0.46%	0.14%	0.42%	0.26%	0.86%	27.42%	7.77%	0.29%	0.68%	30.21%	7.77%
Total	2,291	4,087	20,457	481	120,647	3,495	57,768	209,226	136,132	21,064	52,030	209,226
	1.09%	**1.95%**	**9.78%**	**0.23%**	**57.66%**	**1.67%**	**27.61%**	**100.00%**	**65.06%**	**10.07%**	**24.87%**	**100.00%**
	1.09%	*1.95%*	*9.78%*	*0.23%*	*57.66%*	*1.67%*	*27.61%*	*100.00%*	*65.06%*	*10.07%*	*24.87%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	209	24	280	19	4936	172	6,727	12,367	30,731
	0.99%	**0.11%**	**1.33%**	**0.09%**	**23.43%**	**0.82%**	**31.94%**	**58.71%**	**14.69%**
	1.69%	*0.19%*	*2.26%*	*0.15%*	*39.91%*	*1.39%*	*54.39%*	*100.00%*	*28.72%*
	69.90%	54.55%	61.67%	79.17%	67.09%	54.09%	53.52%	58.71%	60.57%
Male	89	20	174	5	2421	145	5,700	8,554	19,771
	0.42%	**0.09%**	**0.83%**	**0.02%**	**11.49%**	**0.69%**	**27.06%**	**40.61%**	**9.45%**
	1.04%	*0.23%*	*2.03%*	*0.06%*	*28.30%*	*1.70%*	*66.64%*	*100.00%*	*23.00%*
	29.77%	45.45%	38.33%	20.83%	32.91%	45.60%	45.35%	40.61%	38.97%
Unknown	1	0	0	0	0	1	141	143	234
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.67%**	**0.68%**	**0.11%**
	0.70%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.70%*	*98.60%*	*100.00%*	*1.44%*
	0.33%	0.00%	0.00%	0.00%	0.00%	0.31%	1.12%	0.68%	0.46%
TOTAL	299	44	454	24	7,357	318	12,568	21,064	50,736
	1.42%	**0.21%**	**2.16%**	**0.11%**	**34.93%**	**1.51%**	**59.67%**	**100.00%**	**24.25%**
	1.42%	*0.21%*	*2.16%*	*0.11%*	*34.93%*	*1.51%*	*59.67%*	*100.00%*	*24.25%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 14A

Number of Protocols with Enrollment Data: **193**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	415	2,188	10,067	3,966	87,984	2,154	106,774	16,636
	0.22%	**1.18%**	**5.42%**	**2.14%**	**47.38%**	**1.16%**	**57.50%**	**8.96%**
	0.39%	*2.05%*	*9.43%*	*3.71%*	*82.40%*	*2.02%*	*100.00%*	*15.58%*
	57.24%	62.62%	50.68%	44.99%	59.19%	51.79%	57.50%	50.57%
Male	310	1,306	9,795	4,850	60,653	2,001	78,915	16,261
	0.17%	**0.70%**	**5.27%**	**2.61%**	**32.66%**	**1.08%**	**42.49%**	**8.76%**
	0.39%	*1.65%*	*12.41%*	*6.15%*	*76.86%*	*2.54%*	*100.00%*	*20.61%*
	42.76%	37.38%	49.31%	55.01%	40.80%	48.11%	42.49%	49.43%
Unknown	0	0	1	0	16	4	21	1
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*4.76%*	*0.00%*	*76.19%*	*19.05%*	*100.00%*	*4.76%*
	0.00%	0.00%	0.01%	0.00%	0.01%	0.10%	0.01%	0.00%
Total	725	3,494	19,863	8,816	148,653	4,159	185,710	32,898
	0.39%	**1.88%**	**10.70%**	**4.75%**	**80.05%**	**2.24%**	**100.00%**	**17.71%**
	0.39%	*1.88%*	*10.70%*	*4.75%*	*80.05%*	*2.24%*	*100.00%*	*17.71%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (213,778 or 54.13%) than males (164,887 or 41.75%) were enrolled in aggregate Domestic Extramural Phase III Research Protocols.
More minority females (47,367 or 56.64%) than males (36,032 or 43.08%) are enrolled in aggregate Domestic Extramural Phase III Research Protocols.

Race

Approximately 21.18% (83,634) of participants in aggregate Domestic Extramural Phase III Research (394,936 total) were classified as U.S. minorities.
Largest identified racial group was White at 80.05% following the 1977 OMB standards and 57.66% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 10.70% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 9.78% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.23%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.39%.

Ethnicity

10.07% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 59.67% (2nd largest category was White at 34.93%).
Smallest identified racial group was Hawaiian/Pacific Islander at 0.11%.
Of the 21,064 participants, 58.71% were women and 40.61% were men.
4.75% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 15A. DOMESTIC Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	14,511	2,110		14.54%
%	43.31%	44.85%		
Males	18,991	2,595		13.66%
%	56.68%	55.15%		
Unknown	2	0		0.00%
%	0.01%	0.00%		
TOTAL	33,504	4,705	14.04%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	32

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	21

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	11	95	452	72	5,366	266	167	6,429	5,924	297	208	6,429
	0.10%	**0.85%**	**4.03%**	**0.64%**	**47.79%**	**2.37%**	**1.49%**	**57.25%**	**52.76%**	**2.64%**	**1.85%**	**57.25%**
	0.17%	*1.48%*	*7.03%*	*1.12%*	*83.47%*	*4.14%*	*2.60%*	*100.00%*	*92.14%*	*4.62%*	*3.24%*	*100.00%*
	47.83%	45.89%	66.08%	100.00%	56.86%	55.53%	51.23%	57.25%	57.24%	55.41%	60.64%	57.25%
Male	12	112	232	0	4,072	213	157	4,798	4,426	239	133	4,798
	0.11%	**1.00%**	**2.07%**	**0.00%**	**36.26%**	**1.90%**	1.40%	**42.73%**	**39.42%**	**2.13%**	**1.18%**	**42.73%**
	0.25%	*2.33%*	*4.84%*	*0.00%*	*84.87%*	*4.44%*	3.27%	*100.00%*	*92.25%*	*4.98%*	*2.77%*	*100.00%*
	52.17%	54.11%	33.92%	0.00%	43.14%	44.47%	48.16%	42.73%	42.76%	44.59%	38.78%	42.73%
Unknown	0	0	0	0	0	0	2	2	0	0	2	2
	0.00%	**0.00%**	**0.00%**	0.00%	**0.00%**	**0.00%**	***0.02%***	**0.02%**	**0.00%**	**0.00%**	**0.02%**	**0.02%**
	0.00%	*0.00%*	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.61%	0.02%	0.00%	0.00%	0.58%	0.02%
Total	23	207	684	72	9,438	479	326	11,229	10,350	536	343	11,229
	0.20%	**1.84%**	**6.09%**	**0.64%**	**84.05%**	**4.27%**	**2.90%**	**100.00%**	**92.17%**	**4.77%**	**3.05%**	**100.00%**
	0.20%	*1.84%*	*6.09%*	*0.64%*	*84.05%*	*4.27%*	*2.90%*	*100.00%*	*92.17%*	*4.77%*	*3.05%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1	0	0	0	2	1	293	297	1,191
	0.19%	**0.00%**	**0.00%**	**0.00%**	**0.37%**	**0.19%**	**54.66%**	**55.41%**	**10.61%**
	0.34%	*0.00%*	*0.00%*	*0.00%*	*0.67%*	*0.34%*	*98.65%*	*100.00%*	*18.53%*
	100.00%	0.00%	0.00%	0.00%	66.67%	100.00%	55.18%	55.41%	59.58%
Male	0	0	0	0	1	0	238	239	808
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.19%**	**0.00%**	**44.40%**	**44.59%**	**7.20%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.42%*	*0.00%*	*99.58%*	*100.00%*	*16.84%*
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	44.82%	44.59%	40.42%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	1	0	0	0	3	1	531	536	1,999
	0.19%	**0.00%**	**0.00%**	**0.00%**	**0.56%**	**0.19%**	**99.07%**	**100.00%**	**17.80%**
	0.19%	*0.00%*	*0.00%*	*0.00%*	*0.56%*	*0.19%*	*99.07%*	*100.00%*	*17.80%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 15A

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

Number of Protocols with Enrollment Data: **11**

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	6	169	570	174	7,132	31	8,082	919
	0.03%	**0.76%**	**2.56%**	**0.78%**	**32.02%**	**0.14%**	**36.28%**	**4.13%**
	0.07%	*2.09%*	*7.05%*	*2.15%*	*88.25%*	*0.38%*	*100.00%*	*11.37%*
	23.08%	37.81%	33.18%	33.79%	36.62%	32.63%	36.28%	33.96%
Male	20	278	1,148	341	12,342	64	14,193	1,787
	0.09%	**1.25%**	**5.15%**	**1.53%**	**55.41%**	**0.29%**	**63.72%**	**8.02%**
	0.14%	*1.96%*	*8.09%*	*2.40%*	*86.96%*	*0.45%*	*100.00%*	*12.59%*
	76.92%	62.19%	66.82%	66.21%	63.38%	67.37%	63.72%	66.04%
Unknown	0	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	26	447	1,718	515	19,474	95	22,275	2,706
	0.12%	**2.01%**	**7.71%**	**2.31%**	**87.43%**	**0.43%**	**100.00%**	**12.15%**
	0.12%	*2.01%*	*7.71%*	*2.31%*	*87.43%*	*0.43%*	*100.00%*	*12.15%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More males (18,991 or 56.68%) than females (14,511 or 43.31%) were enrolled in aggregate Domestic Intramural Phase III Research Protocols.
More minority males (2,595 or 55.15%) than females (2,110 or 44.85%) were enrolled in aggregate Domestic Intramural Phase III Research Protocols.

Race

Approximately 14.04% (4,705) of participants in aggregate Domestic Intramural Phase III Research (33,504 total) were classified as U.S. minorities.
Largest identified racial group was White at 87.43% following the 1977 OMB standards and 84.05% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 7.71% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 6.09% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.20%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.12%.

Ethnicity

4.77% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 99.07% (2nd largest category was White at 0.56%).
Asian, Black/African American and Hawaiian/Pacific Islander were the smallest identified racial groups with 0.0%.
Of the 536 participants, 55.41% were women and 44.59% were men.
2.31% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 16A. FOREIGN Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	754,633	577,468		76.52%
%	59.52%	61.91%		
Males	497,976	348,190		69.92%
%	39.28%	37.33%		
Unknown	15,261	7,038		46.12%
%	1.20%	0.75%		
TOTAL	1,267,870	932,696	73.56%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	451

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 445

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	8,521	308,787	153,629	5,547	168,457	4,168	104,099	753,208	607,469	110,806	34,932	753,207
	0.67%	24.42%	12.15%	0.44%	13.32%	0.33%	8.23%	59.56%	48.03%	8.76%	2.76%	59.56%
	1.13%	41.00%	20.40%	0.74%	22.37%	0.55%	13.82%	100.00%	80.65%	14.71%	4.64%	100.00%
	54.67%	66.48%	52.42%	52.43%	53.91%	51.69%	64.90%	59.56%	59.22%	66.43%	48.43%	59.56%
Male	6,940	154,807	136,670	4,816	138,196	3,726	51,038	496,193	408,612	52,830	34,749	496,191
	0.55%	12.24%	10.81%	0.38%	10.93%	0.29%	4.04%	39.24%	32.31%	4.18%	2.75%	39.24%
	1.40%	31.20%	27.54%	0.97%	27.85%	0.75%	10.29%	100.00%	82.35%	10.65%	7.00%	100.00%
	44.52%	33.33%	46.63%	45.52%	44.22%	46.21%	31.82%	39.24%	39.84%	31.67%	48.17%	39.24%
Unknown	126	896	2,765	217	5838	169	5,250	15,261	9,652	3,154	2,455	15,261
	0.01%	0.07%	0.22%	0.02%	0.46%	0.01%	0.42%	1.21%	0.76%	0.25%	0.19%	1.21%
	0.83%	5.87%	18.12%	1.42%	38.25%	1.11%	34.40%	100.00%	63.25%	20.67%	16.09%	100.00%
	0.81%	0.19%	0.94%	2.05%	1.87%	2.10%	3.27%	1.21%	0.94%	1.89%	3.40%	1.21%
Total	15,587	464,490	293,064	10,580	312,491	8,063	160,387	1,264,662	1,025,733	166,790	72,136	1,264,659
	1.23%	36.73%	23.17%	0.84%	24.71%	0.64%	12.68%	100.00%	81.11%	13.19%	5.70%	100.00%
	1.23%	36.73%	23.17%	0.84%	24.71%	0.64%	12.68%	100.00%	81.11%	13.19%	5.70%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	9,042	283	1813	486	25,043	3,063	71,076	110,806	576,771
	5.42%	0.17%	1.09%	0.29%	15.01%	1.84%	42.61%	66.43%	45.61%
	8.16%	0.26%	1.64%	0.44%	22.60%	2.76%	64.14%	100.00%	76.58%
	54.21%	51.45%	56.06%	43.59%	54.40%	52.67%	76.13%	66.43%	61.94%
Male	7,503	267	1386	629	20,991	2,635	19,419	52,830	347,369
	4.50%	0.16%	0.83%	0.38%	12.59%	1.58%	11.64%	31.67%	27.47%
	14.20%	0.51%	2.62%	1.19%	39.73%	4.99%	36.76%	100.00%	70.01%
	44.98%	48.55%	42.86%	56.41%	45.60%	45.31%	20.80%	31.67%	37.30%
Unknown	136	0	35	0	0	118	2,865	3,154	7,038
	0.08%	0.00%	0.02%	0.00%	0.00%	0.07%	1.72%	1.89%	0.56%
	4.31%	0.00%	1.11%	0.00%	0.00%	3.74%	90.84%	100.00%	46.12%
	0.82%	0.00%	1.08%	0.00%	0.00%	2.03%	3.07%	1.89%	0.76%
TOTAL	16,681	550	3,234	1,115	46,034	5,816	93,360	166,790	931,178
	10.00%	0.33%	1.94%	0.67%	27.60%	3.49%	55.97%	100.00%	73.63%
	10.00%	0.33%	1.94%	0.67%	27.60%	3.49%	55.97%	100.00%	73.63%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 16A

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

Number of Protocols with Enrollment Data: **6**

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	0	2	0	695	725	3	1,425	697
	0.00%	**0.06%**	**0.00%**	**21.66%**	**22.60%**	**0.09%**	**44.42%**	**21.73%**
	0.00%	*0.14%*	*0.00%*	*48.77%*	*50.88%*	*0.21%*	*100.00%*	*48.91%*
	0.00%	100.00%	0.00%	45.87%	43.03%	60.00%	44.42%	45.92%
Male	0	0	1	820	960	2	1,783	821
	0.00%	**0.00%**	**0.03%**	**25.56%**	**29.93%**	**0.06%**	**55.58%**	**25.59%**
	0.00%	*0.00%*	*0.06%*	*45.99%*	*53.84%*	*0.11%*	*100.00%*	*46.05%*
	0.00%	0.00%	100.00%	54.13%	56.97%	40.00%	55.58%	54.08%
Unknown	0	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	2	1	1,515	1,685	5	3,208	1,518
	0.00%	**0.06%**	**0.03%**	**47.23%**	**52.52%**	**0.16%**	**100.00%**	**47.32%**
	0.00%	*0.06%*	*0.03%*	*47.23%*	*52.52%*	*0.16%*	*100.00%*	*47.32%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (754,632 or 59.52%) than males (497,974 or 39.28%) were enrolled in aggregate Foreign Intramural and Extramural Research Protocols.
More minority females (577,468 or 61.91%) than males (348,190 or 37.33%) were enrolled in aggregate Foreign Intramural and Extramural Research Protocols.

Race

Approximately 73.56% (932,686) of participants in aggregate Foreign Intramural and Extramural Research (1,267,857 total) were classified as minorities.
Largest identified racial group was White at 52.52% following the 1977 OMB standards.
Largest identified racial group was Asian at 36.73% following the 1997 OMB standards (with 24.71%, White was not the largest identified racial group).
Largest identified racial minority group was Hispanic at 47.23% following the 1977 OMB standards.
Largest identified racial minority group was Asian at 36.73% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.84%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.0%.

Ethnicity

13.19% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 55.97% (2nd largest category was White at 27.60%).
Smallest identified racial group was Asian at 0.33%.
Of the 166,790 participants, 66.43% were women and 31.67% were men.
47.23% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 17A. FOREIGN Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**521,771**	**442,240**		**84.76%**
%	**57.28%**	**59.26%**		
Males	**377,384**	**297,674**		**78.88%**
%	**41.43%**	**39.89%**		
Unknown	**11,776**	**6,364**		**54.04%**
%	**1.29%**	**0.85%**		
TOTAL	**910,931**	**746,278**	**81.92%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **380**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **374**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	8,517	198,949	150,934	5,545	78,864	2,310	75,227	520,346	410,918	87,020	22,408	520,346
	0.94%	**21.92%**	**16.63%**	**0.61%**	**8.69%**	**0.25%**	**8.29%**	**57.32%**	**45.27%**	**9.59%**	**2.47%**	**57.32%**
	1.64%	*38.23%*	*29.01%*	*1.07%*	*15.16%*	*0.44%*	*14.46%*	*100.00%*	*78.97%*	*16.72%*	*4.31%*	*100.00%*
	54.66%	64.08%	52.66%	52.42%	49.26%	49.32%	62.87%	57.32%	56.71%	62.80%	50.23%	57.32%
Male	6,940	111,316	132,918	4,816	77,894	2,205	39,512	375,601	307,133	48,408	20,060	375,601
	0.76%	**12.26%**	**14.64%**	**0.53%**	**8.58%**	**0.24%**	4.35%	**41.38%**	**33.84%**	**5.33%**	**2.21%**	**41.38%**
	1.85%	*29.64%*	*35.39%*	*1.28%*	*20.74%*	*0.59%*	10.52%	*100.00%*	*81.77%*	*12.89%*	*5.34%*	*100.00%*
	44.54%	35.85%	46.37%	45.53%	48.65%	47.08%	33.02%	41.38%	42.39%	34.93%	44.96%	41.38%
Unknown	126	222	2,765	217	3,353	169	4,924	11,776	6,493	3,138	2,145	11,776
	0.01%	**0.02%**	**0.30%**	0.02%	**0.37%**	**0.02%**	***0.54%***	**1.30%**	**0.72%**	**0.35%**	**0.24%**	**1.30%**
	1.07%	*1.89%*	*23.48%*	1.84%	*28.47%*	*1.44%*	*41.81%*	*100.00%*	*55.14%*	*26.65%*	*18.22%*	*100.00%*
	0.81%	0.07%	0.96%	2.05%	2.09%	3.61%	4.11%	1.30%	0.90%	2.26%	4.81%	1.30%
Total	15,583	310,487	286,617	10,578	160,111	4,684	119,663	907,723	724,544	138,566	44,613	907,723
	1.72%	**34.21%**	**31.58%**	**1.17%**	**17.64%**	**0.52%**	**13.18%**	**100.00%**	**79.82%**	**15.27%**	**4.91%**	**100.00%**
	1.72%	*34.21%*	*31.58%*	*1.17%*	*17.64%*	*0.52%*	*13.18%*	*100.00%*	*79.82%*	*15.27%*	*4.91%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	7,896	283	1,735	485	23,511	1,333	51,777	87,020	441,543
	5.70%	**0.20%**	**1.25%**	**0.35%**	**16.97%**	**0.96%**	**37.37%**	**62.80%**	**48.64%**
	9.07%	*0.33%*	*1.99%*	*0.56%*	*27.02%*	*1.53%*	*59.50%*	*100.00%*	*84.86%*
	55.16%	51.45%	55.77%	43.54%	54.47%	50.02%	70.31%	62.80%	59.29%
Male	6,299	267	1,341	629	19,654	1,214	19,004	48,408	296,853
	4.55%	**0.19%**	**0.97%**	**0.45%**	**14.18%**	**0.88%**	**13.71%**	**34.93%**	**32.70%**
	13.01%	*0.55%*	*2.77%*	*1.30%*	*40.60%*	*2.51%*	*39.26%*	*100.00%*	*79.03%*
	44.00%	48.55%	43.11%	56.46%	45.53%	45.55%	25.80%	34.93%	39.86%
Unknown	120	0	35	0	0	118	2,865	3,138	6,364
	0.09%	**0.00%**	**0.03%**	**0.00%**	**0.00%**	**0.09%**	**2.07%**	**2.26%**	**0.70%**
	3.82%	*0.00%*	*1.12%*	*0.00%*	*0.00%*	*3.76%*	*91.30%*	*100.00%*	*54.04%*
	0.84%	0.00%	1.13%	0.00%	0.00%	4.43%	3.89%	2.26%	0.85%
TOTAL	14,315	550	3,111	1,114	43,165	2,665	73,646	138,566	744,760
	10.33%	**0.40%**	**2.25%**	**0.80%**	**31.15%**	**1.92%**	**53.15%**	**100.00%**	**82.05%**
	10.33%	*0.40%*	*2.25%*	*0.80%*	*31.15%*	*1.92%*	*53.15%*	*100.00%*	*82.05%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 17A

Number of Protocols with Enrollment Data: 6

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	2	0	695	725	3	1,425	697
	0.00%	**0.06%**	**0.00%**	**21.66%**	**22.60%**	**0.09%**	**44.42%**	**21.73%**
	0.00%	*0.14%*	*0.00%*	*48.77%*	*50.88%*	*0.21%*	*100.00%*	*48.91%*
	0.00%	100.00%	0.00%	45.87%	43.03%	60.00%	44.42%	45.92%
Male	0	0	1	820	960	2	1,783	821
	0.00%	**0.00%**	**0.03%**	**25.56%**	**29.93%**	**0.06%**	**55.58%**	**25.59%**
	0.00%	*0.00%*	*0.06%*	*45.99%*	*53.84%*	*0.11%*	*100.00%*	*46.05%*
	0.00%	0.00%	100.00%	54.13%	56.97%	40.00%	55.58%	54.08%
Unknown	0	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	2	1	1,515	1,685	5	3,208	1,518
	0.00%	**0.06%**	**0.03%**	**47.23%**	**52.52%**	**0.16%**	**100.00%**	**47.32%**
	0.00%	*0.06%*	*0.03%*	*47.23%*	*52.52%*	*0.16%*	*100.00%*	*47.32%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (521,770 or 57.28%) than males (377,382 or 41.43%) were enrolled in aggregate Foreign Extramural Research Protocols.
More minority females (442,240 or 59.26%) than males (297,674 or 39.89%) were enrolled in aggregate Foreign Extramural Research Protocols.

Race

Approximately 81.93% (746,278) of participants in aggregate Foreign Extramural Research (910,928 total) were classified as minorities.
Largest identified racial group was White at 52.52% following the 1977 OMB standards.
Largest identified racial group was Asian at 34.21% following the 1997 OMB standards.
Largest identified racial minority group was Hispanic at 47.23% following the 1977 OMB standards.
Largest identified racial minority group was Asian at 34.21% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was More Than One Race at 0.52%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.0%.

Ethnicity

15.27% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 53.15% (2nd largest category was White at 31.15%).
Smallest identified racial group was Asian at 0.40%.
Of the 138,566 participants, 62.80% were women and 34.93% were men.
47.23% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 18A. FOREIGN Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**232,862**	**135,228**		**58.07%**
%	**65.24%**	**72.54%**		
Males	**120,592**	**50,516**		**41.89%**
%	**33.79%**	**27.10%**		
Unknown	**3,485**	**674**		**19.34%**
%	**0.98%**	**0.36%**		
TOTAL	**356,939**	**186,418**	**52.23%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **71**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **71**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	4	109,838	2,695	2	89,593	1,858	28,872	232,862	196,552	23,786	12,524	232,862
	0.00%	**30.77%**	**0.76%**	**0.00%**	**25.10%**	**0.52%**	**8.09%**	**65.24%**	**55.07%**	**6.66%**	**3.51%**	**65.24%**
	0.00%	*47.17%*	*1.16%*	*0.00%*	*38.47%*	*0.80%*	*12.40%*	*100.00%*	*84.41%*	*10.21%*	*5.38%*	*100.00%*
	100.00%	71.32%	41.80%	100.00%	58.80%	54.99%	70.90%	65.24%	65.26%	84.28%	45.50%	65.24%
Male	0	43,491	3,752	0	60,302	1,521	11,526	120,592	101,481	4,422	14,689	120,592
	0.00%	**12.18%**	**1.05%**	**0.00%**	**16.89%**	**0.43%**	3.23%	**33.79%**	**28.43%**	**1.24%**	**4.12%**	**33.79%**
	0.00%	*36.06%*	*3.11%*	*0.00%*	*50.00%*	*1.26%*	9.56%	*100.00%*	*84.15%*	*3.67%*	*12.18%*	*100.00%*
	0.00%	28.24%	58.20%	0.00%	39.57%	45.01%	28.30%	33.79%	33.69%	15.67%	53.37%	33.79%
Unknown	0	674	0	0	2,485	0	326	3,485	3,159	16	310	3,485
	0.00%	**0.19%**	**0.00%**	0.00%	**0.70%**	**0.00%**	***0.09%***	**0.98%**	**0.89%**	**0.00%**	**0.09%**	**0.98%**
	0.00%	*19.34%*	*0.00%*	0.00%	*71.31%*	*0.00%*	*9.35%*	*100.00%*	*90.65%*	*0.46%*	*8.90%*	*100.00%*
	0.00%	0.44%	0.00%	0.00%	1.63%	0.00%	0.80%	0.98%	1.05%	0.06%	1.13%	0.98%
Total	4	154,003	6,447	2	152,380	3,379	40,724	356,939	301,192	28,224	27,523	356,939
	0.00%	**43.15%**	**1.81%**	**0.00%**	**42.69%**	**0.95%**	**11.41%**	**100.00%**	**84.38%**	**7.91%**	**7.71%**	**100.00%**
	0.00%	*43.15%*	*1.81%*	*0.00%*	*42.69%*	*0.95%*	*11.41%*	*100.00%*	*84.38%*	*7.91%*	*7.71%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1,146	0	78	1	1,532	1,730	19,299	23,786	135,228
	4.06%	**0.00%**	**0.28%**	**0.00%**	**5.43%**	**6.13%**	**68.38%**	**84.28%**	**37.89%**
	4.82%	*0.00%*	*0.33%*	*0.00%*	*6.44%*	*7.27%*	*81.14%*	*100.00%*	*58.07%*
	48.44%	0.00%	63.41%	100.00%	53.40%	54.90%	97.89%	84.28%	72.54%
Male	1,204	0	45	0	1,337	1,421	415	4,422	50,516
	4.27%	**0.00%**	**0.16%**	**0.00%**	**4.74%**	**5.03%**	**1.47%**	**15.67%**	**14.15%**
	27.23%	*0.00%*	*1.02%*	*0.00%*	*30.24%*	*32.13%*	*9.38%*	*100.00%*	*41.89%*
	50.89%	0.00%	36.59%	0.00%	46.60%	45.10%	2.11%	15.67%	27.10%
Unknown	16	0	0	0	0	0	0	16	674
	0.06%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.06%**	**0.19%**
	100.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*19.34%*
	0.68%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.06%	0.36%
TOTAL	2,366	0	123	1	2,869	3,151	19,714	28,224	186,418
	8.38%	**0.00%**	**0.44%**	**0.00%**	**10.17%**	**11.16%**	**69.85%**	**100.00%**	**52.23%**
	8.38%	*0.00%*	*0.44%*	*0.00%*	*10.17%*	*11.16%*	*69.85%*	*100.00%*	*52.23%*
	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 18A

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

Number of Protocols with Enrollment Data: **0**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Male	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Unknown	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

More females (232,862 or 65.24%) than males (120,592 or 33.79%) were enrolled in aggregate Foreign intramural research protocols.
More minority females (135,228 or 72.54%) than males (50,516 or 27.10%) were enrolled in aggregate Foreign intramural research protocols.

Race

Approximately 52.23% (186,418) of participants in aggregate Foreign intramural research (356,939 total) were classified as minorities.
Largest identified racial group was Asian at 43.15% following the 1997 OMB standards.
Largest identified racial minority group was Asian at 43.15% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minorites were Hawaiian/Pacific Islander and American Indian/Alaska Native both at 0.0%.
NOTE: The data represented in Table 18A required no forgein reporting using the 1977 OMB Standards.

Ethnicity

7.91% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 69.85%.
Smallest identified racial groups were Asian and Hawaiian/Pacific Islander at 0.0%.
Of the 28,224 participants, 84.28% were women and 15.67% were men.

Table 19A. FOREIGN Aggregate Enrollment Data for Phase III Extramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**87,957**	**86,903**		**98.80%**
%	**57.58%**	**58.16%**		
Males	**64,235**	**61,962**		**96.46%**
%	**42.05%**	**41.47%**		
Unknown	**559**	**559**		**100.00%**
%	**0.37%**	**0.37%**		
TOTAL	**152,751**	**149,424**	**97.82%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **40**

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **39**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	3,658	20,416	31,200	1	855	23	31,084	87,237	51,959	35,262	16	87,237
	2.42%	**13.51%**	**20.65%**	**0.00%**	**0.57%**	**0.02%**	**20.57%**	**57.74%**	**34.39%**	**23.34%**	**0.01%**	**57.74%**
	4.19%	*23.40%*	*35.76%*	*0.00%*	*0.98%*	*0.03%*	*35.63%*	*100.00%*	*59.56%*	*40.42%*	*0.02%*	*100.00%*
	51.98%	47.40%	49.39%	50.00%	29.31%	13.45%	89.55%	57.74%	48.09%	81.99%	100.00%	57.74%
Male	3,347	22,638	31,595	1	2,060	106	3,536	63,283	55,661	7,622	0	63,283
	2.22%	**14.98%**	**20.91%**	**0.00%**	**1.36%**	**0.07%**	2.34%	**41.89%**	**36.84%**	**5.05%**	**0.00%**	**41.89%**
	5.29%	*35.77%*	*49.93%*	*0.00%*	*3.26%*	*0.17%*	5.59%	*100.00%*	*87.96%*	*12.04%*	*0.00%*	*100.00%*
	47.56%	52.56%	50.01%	50.00%	70.62%	61.99%	10.19%	41.89%	51.51%	17.72%	0.00%	41.89%
Unknown	32	16	377	0	2	42	90	559	435	124	0	559
	0.02%	**0.01%**	**0.25%**	0.00%	**0.00%**	**0.03%**	***0.06%***	**0.37%**	**0.29%**	**0.08%**	**0.00%**	**0.37%**
	5.72%	*2.86%*	*67.44%*	0.00%	*0.36%*	*7.51%*	*16.10%*	*100.00%*	*77.82%*	*22.18%*	*0.00%*	*100.00%*
	0.45%	0.04%	0.60%	0.00%	0.07%	24.56%	0.26%	0.37%	0.40%	0.29%	0.00%	0.37%
Total	7,037	43,070	63,172	2	2,917	171	34,710	151,079	108,055	43,008	16	151,079
	4.66%	**28.51%**	**41.81%**	**0.00%**	**1.93%**	**0.11%**	**22.97%**	**100.00%**	**71.52%**	**28.47%**	**0.01%**	**100.00%**
	4.66%	*28.51%*	*41.81%*	*0.00%*	*1.93%*	*0.11%*	*22.97%*	*100.00%*	*71.52%*	*28.47%*	*0.01%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	3,657	0	1	0	8	2	31,594	35,262	86,900
	8.50%	**0.00%**	**0.00%**	**0.00%**	**0.02%**	**0.00%**	**73.46%**	**81.99%**	**57.52%**
	10.37%	*0.00%*	*0.00%*	*0.00%*	*0.02%*	*0.01%*	*89.60%*	*100.00%*	*99.61%*
	52.00%	0.00%	25.00%	0.00%	11.43%	66.67%	88.01%	81.99%	58.16%
Male	3,344	1	3	0	62	1	4,211	7,622	61,960
	7.78%	**0.00%**	**0.01%**	**0.00%**	**0.14%**	**0.00%**	**9.79%**	**17.72%**	**41.01%**
	43.87%	*0.01%*	*0.04%*	*0.00%*	*0.81%*	*0.01%*	*55.25%*	*100.00%*	*97.91%*
	47.55%	100.00%	75.00%	0.00%	88.57%	33.33%	11.73%	17.72%	41.47%
Unknown	32	0	0	0	0	0	92	124	559
	0.07%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.21%**	**0.29%**	**0.37%**
	25.81%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*74.19%*	*100.00%*	*100.00%*
	0.45%	0.00%	0.00%	0.00%	0.00%	0.00%	0.26%	0.29%	0.37%
TOTAL	7,033	1	4	0	70	3	35,897	43,008	149,419
	16.35%	**0.00%**	**0.01%**	**0.00%**	**0.16%**	**0.01%**	**83.47%**	**100.00%**	**98.90%**
	16.35%	*0.00%*	*0.01%*	*0.00%*	*0.16%*	*0.01%*	*83.47%*	*100.00%*	*98.90%*
	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 19A

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

Number of Protocols with Enrollment Data: **1**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	2	0	1	714	3	720	3
	0.00%	**0.12%**	**0.00%**	**0.06%**	**42.70%**	**0.18%**	**43.06%**	**0.18%**
	0.00%	*0.28%*	*0.00%*	*0.14%*	*99.17%*	*0.42%*	*100.00%*	*0.42%*
	0.00%	100.00%	0.00%	50.00%	42.96%	60.00%	43.06%	60.00%
Male	0	0	1	1	948	2	952	2
	0.00%	**0.00%**	**0.06%**	**0.06%**	**56.70%**	**0.12%**	**56.94%**	**0.12%**
	0.00%	*0.00%*	*0.11%*	*0.11%*	*99.58%*	*0.21%*	*100.00%*	*0.21%*
	0.00%	0.00%	100.00%	50.00%	57.04%	40.00%	56.94%	40.00%
Unknown	0	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	2	1	2	1,662	5	1,672	5
	0.00%	**0.12%**	**0.06%**	**0.12%**	**99.40%**	**0.30%**	**100.00%**	**0.30%**
	0.00%	*0.12%*	*0.06%*	*0.12%*	*99.40%*	*0.30%*	*100.00%*	*0.30%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender:
More females (87,957; 57.58%) than males (64,235; 42.05%) were enrolled in Aggregate Foreign Phase III Extramural Research Protocols.
More minority females (86,903; 58.16%) than males (61,962; 41.47%) were enrolled in Aggregate Foreign Phase III Extramural Research Protocols.

Race
Approximately 97.82% (149,424) of participants in aggregate Foreign Phase III Extramural Research (152,751 total) were classified as minorities.
Largest identified racial group was White at 99.40% following the 1977 OMB standards.
Largest identified racial group was Black/African American at 41.81% following the 1997 OMB standards.
Largest identified racial minority groups were Hispanic and Asian/Pacific Islander at 0.12% following the 1977 OMB standards.
Largest identified racial minority group was Black/African American at 41.81% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.0%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.0%.

Ethnicity
28.47% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 83.47% (2nd largest category was American Indian/Alaska Native at 16.35%).
Smallest identified racial groups were Asian and Hawaiian/Pacific Islander at 0.00%.
Of the 43,008 participants, 81.99% were women and 17.72% were men.
0.12% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 20A. <u>FOREIGN</u> Aggregate Enrollment Data for <u>Phase III Intramural Research Protocols</u> Funded in FY2006 and Reported in FY2007: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	8,448	7,102		84.07%
%	84.75%	99.07%		
Males	1,520	67		4.41%
%	15.25%	0.93%		
Unknown	0	0		0.00%
%	0.00%	0.00%		
TOTAL	9,968	7,169	71.92%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 4

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 4

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	0	0	92	0	0	0	8,356	8,448	92	7,010	1,346	8,448
	0.00%	**0.00%**	**0.92%**	**0.00%**	**0.00%**	**0.00%**	**83.83%**	**84.75%**	**0.92%**	**70.33%**	**13.50%**	**84.75%**
	0.00%	*0.00%*	*1.09%*	*0.00%*	*0.00%*	*0.00%*	*98.91%*	*100.00%*	*1.09%*	*82.98%*	*15.93%*	*100.00%*
	0.00%	0.00%	59.35%	0.00%	0.00%	0.00%	85.15%	84.75%	59.35%	99.94%	48.09%	84.75%
Male	0	0	63	0	0	0	1,457	1,520	63	4	1,453	1,520
	0.00%	**0.00%**	**0.63%**	**0.00%**	**0.00%**	**0.00%**	14.62%	**15.25%**	**0.63%**	**0.04%**	**14.58%**	**15.25%**
	0.00%	*0.00%*	*4.14%*	*0.00%*	*0.00%*	*0.00%*	95.86%	*100.00%*	*4.14%*	*0.26%*	*95.59%*	*100.00%*
	0.00%	0.00%	40.65%	0.00%	0.00%	0.00%	14.85%	15.25%	40.65%	0.06%	51.91%	15.25%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	0.00%	**0.00%**	**0.00%**	*0.00%*	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	155	0	0	0	9,813	9,968	155	7,014	2,799	9,968
	0.00%	**0.00%**	**1.55%**	**0.00%**	**0.00%**	**0.00%**	**98.45%**	**100.00%**	**1.55%**	**70.37%**	**28.08%**	**100.00%**
	0.00%	*0.00%*	*1.55%*	*0.00%*	*0.00%*	*0.00%*	*98.45%*	*100.00%*	*1.55%*	*70.37%*	*28.08%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	0	0	0	0	0	0	7,010	7,010	7,102
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**99.94%**	**99.94%**	**71.25%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*84.07%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	99.94%	99.94%	99.07%
Male	0	0	0	0	0	0	4	4	67
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.06%**	**0.06%**	**0.67%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*4.41%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.06%	0.06%	0.93%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*#DIV/0!*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	0	7,014	7,014	7,169
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**100.00%**	**71.92%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*71.92%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%

Table 20A

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

Number of Protocols with Enrollment Data: **0**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Male	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Unknown	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Legend

Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)

Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)

Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender:
More females (8,448; 84.75%) than males (1,520; 15.25%) were enrolled in aggregate Foreign Phase III Intramural Research Protocols.
More minority females (7,102; 99.07%) than males (67; 0.93%) were enrolled in aggregate Foreign Phase III Intramural Research Protocols.

Race
Approximately 71.92% (7,169) of participants in aggregate Foreign Phase III Intramural Research (9,968 total) were classified as minorities.
Largest identified racial group was Unknown/Other at 98.45% following the 1997 OMB standards.
Largest identified racial minority group was Black/African American at 1.55% following the 1997 OMB standards.
According to the 1997 OMB standards the smallest identified racial minorities were, American Indian/Alaska Native, Asian, Hawaiian/Pacific Islander and White at 0.0%.
NOTE: The data represented in Table 20A required no forgein reporting using the 1977 OMB Standards.

Ethnicity
70.37% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 100%.
Of the 7,014 participants, 99.94% were women and 0.06% were men.