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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 2005 and Fiscal Year 2006

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APPENDICES

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

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 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 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.

Continuing Implementation and Monitoring Activities

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, 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. 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 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.

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 Administrator (SRA) orientation on specific issues related to review meetings and proceedings.

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.

Many of the training sessions are available electronically for all NIH staff, and the Office of Extramural Research (OER) has made available existing training materials on the Population tracking system website on the NIH Intranet. 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. Further information regarding training initiatives since the 2000 GAO report is discussed in the background section of the Appendices (See Appendix A)

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

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 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. 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.

Format Changes for Reporting Race and Ethnicity Data

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**	**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).

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 2006 Summary Reports
Twelve -year Trend Summary Reports

Summary Report of NIH Inclusion Data

NIH AGGREGATE POPULATION DATA REPORTED IN FY2005 and FY2006

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 FY2005 and FY2006 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. For this report, the FY2005 and FY2006 data tables have been reformatted and some tables may vary slightly or differ from prior reported summary data in an effort to better clarify reporting.

NIH CLINICAL RESEARCH: Fiscal Years 2005 and 2006

In FY2005, there were 14,798 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,233 protocols reported human subject participation. Of these, 96.4% were domestic protocols and 3.6% were foreign protocols. Approximately 15.7 million participants were enrolled in extramural and intramural research protocols of which 80.6% were domestic participants and 19.4% were foreign participants. Of the 15.7 million participants, 60.4% were women, 37.8% were men and 1.8% did not provide sex identification. Further, 39.7% of the total participants, and 27.4% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (*Table 6*)

Correspondingly, 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 1*)

While the number of participants in all extramural and intramural clinical research decreased (15.7M in FY2005 and 14.8M in FY2006), there was no significant change in the ratio of women and men (60.4%F and 37.8%M in FY2005; and 63.9%F and 34.9%M in FY2006). One large study involving approximately 1.6M participants that ended in FY2005 and therefore was not included in the FY2005 figures, accounted for the net decreased number of participants reported.

NIH Defined Phase III Clinical Research: FY2005 and FY2006

In FY2005, there were 665 extramural and intramural Phase III clinical research protocols, of which 547 protocols reported human subject participation. Of these, 94.5% were domestic protocols and 5.5% were foreign protocols. Approximately 493,000 participants were enrolled in extramural and intramural Phase III research protocols of which 88.8% were domestic participants and 11.2% were foreign participants. Of the 493,000participants, 59% were women, 40% were men and 1% did not provide sex identification. Further, 31.3% of the total participants, and 25.1% of the Domestic-only participants, in Phase III clinical research were reported as minorities following the 1997 OMB categories for race and ethnicity. (*Table 7*)

According to the trend summaries in this report , of the 210 extramural and intramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.5 % and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 6.9%, Asian/Pacific Islanders were 5.6% and Whites (not Hispanic) 73.2% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*Table 7*)

Furthermore, in FY2005, there were 337 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 28.5% and lowest for Hawaiian/Pacific Islanders 0.3%. Asians represented 5.2%, American Indian/Alaska Natives 1.2% and Whites 57.3% of participants. Participants identifying as *More Than One* Race were 1.7% of the total number of participants. In addition, 5.8% did not identify a race category. Of the 337 extramural and intramural Phase III research protocols designating an ethnicity in FY2005, 88.6 % of total participants identified as “Not Hispanic”, 5.9% of the total participants identified as “Hispanic or Latino” and 5.5% 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 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*)

While the number of participants in Phase III extramural and intramural clinical research slightly increased (493,000 in FY2005 and 499,430 in FY2006), there was no significant change in the ratio of women and men (59.0% F and 40.0%M in FY2005; and 62.9%F and 36.0%M in FY2006).

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

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2005 and 2006

In FY2005, there were 13,003 extramural clinical research protocols, including Phase III and other clinical studies, of which 8,763 protocols reported human subject participation as noted in this report's trend summary tables. Approximately 13.8 million participants were enrolled in extramural research protocols of which 62.1% were women, 36.1% were men and 1.9% did not provide sex identification. *(See 2006 Report, Table 2 and Appendix table 3*A)

Correspondingly, 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. *(Table 2 and Appendix Table 3*A)

While the number of participants in all extramural clinical research decreased (13.8 million in FY2005 and 13.02 million in FY2006), there was no significant change in the ratio of women and men (62%F and 36%M in FY2005 and 65%F and 34%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. (52.4%F and 45.8 % M)

NIH Defined Phase III Extramural Clinical Research: FY2005 and FY2006

In FY2005 of the 273 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7%, Asian/Pacific Islanders were 1.9% and Whites (not Hispanic) 76% of the participants. The categories *Hawaiian/Pacific Islande*r and *More Than One Rac*e were not designations with the 1977 OMB standards. *(See 2006 Report*)

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. *(Table 4 and Appendix Table* 5A)

According to trend summaries in the 2006 report, in FY2005, there were 621 extramural Phase III clinical research protocols, of which 511 protocols reported human subject participation. Of these, 88.5% were domestic protocols and 4.9% were foreign protocols. Approximately 465,956 participants were enrolled in extramural Phase III research protocols of which 86% of total enrollment is domestic participants and 8.6% of total enrollment is foreign participants. Of the 465,956 participants, 59.5% were women, 39.5% were men and 1% did not provide sex identification. Further, 29.9% of the total participants in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (*See 2006 Report, Table 4 and Appendix Table 5A*)

Correspondingly, in FY2006, there were 382 extramural Phase III research protocols reporting data following the current 1997 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. (Appendix *Table 5A*)

In FY 2005, there were 319 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 30.00 % and lowest for Hawaiian/Pacific Islanders 0.28%. Asians represented 5.44%, American Indian/Alaska Natives 1.30% and Whites 55.75% of participants. Participants identifying as *More Than One* Race were 1.56% of the total number of participants. In addition, 5.66 % did not identify a race category. Of the 319 extramural Phase III research protocols designating an ethnicity in FY2005, 88.7 % of total participants identified as “Not Hispanic”, 5.98 % of the total participants identified as “Hispanic or Latino”, and 5.32 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (See 2006 Report, *Appendix Table5A*)

Of the 192 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 13.03 and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7.23%, Asian/Pacific Islanders were 1.81% and Whites (not Hispanic) 76.1% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*See 2006 Report, Appendix Table 5A)*

While the number of participants in Phase III extramural clinical research protocols slightly increased, there was also some change in the ratio of women and men (59.5%F and 39.5%M in FY2005 and 63.5 %F and 35.4% M in FY2006).

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2005 and 2006

Substantial numbers of women and minorities were included in NIH intramural studies in FY 2005 and FY2006.

In FY2005, there were 1,795 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,470 protocols reported human subject participation. Of these, 13.7% of the total protocols were domestic protocols and 0.7% of the total protocols were foreign protocols. Approximately 1.94 million participants were enrolled in intramural research protocols of which 10.4% of the total enrollment is domestic participation and 1.9% of the total enrollment is foreign participation. Of the 1.94 million participants, 48.7% were women, 50.5% were men and 0.79% did not provide sex identification. (*See 2006 Report, Table 2 and Appendix Table 7A*)

In FY2005, approximately 1.94 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 733 intramural research protocols that report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 17.8% and lowest for American Indian/Alaska Natives at 1.8%. Blacks (not-Hispanic) represented 7.5%, Hispanics 4.7%; and Whites (not Hispanic) 60.9% 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 2006 Report, Appendix Table 7A*)

For the 737 intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2005 the largest racial minority group was Blacks at 4.74% and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.19%. Asians represented 3.1%, American Indian/Alaska Natives 0.42% and Whites 86.2% of participants in all intramural clinical research. Approximately 1% of participants reported *More Than One Race* as their racial category. In addition, 4.42 % did not identify a race category. Of the 737 intramural research protocols following the current 1997 OMB standards designating an ethnicity in FY 2005, 95.58 % of total participants identified as “Not Hispanic”, 2.10 % of the total participants identified as “Hispanic or Latino”, and 2.32 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (*See 2006 Report, Appendix 7A*)

Correspondingly, 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*)

There was an increase in female participants from 48.7% to 55.4% and a corresponding decrease in male participants from 50.5% to 43.0%. The number of participants in all intramural clinical research decreased slightly from 1.9M to 1.8M from FY2005 to FY2006.

NIH Defined Phase III Intramural Clinical Research: FY2005 and FY2006

In FY2005, there were 44 intramural Phase III clinical research protocols, of which 36 protocols reported human subject participation. Of these, 6% of the total protocols is domestic protocols and 0.5% of the total protocols is foreign protocols. Approximately 27,044 participants were enrolled in intramural Phase III research protocols of which 2.86% of total enrollment is domestic participation and 2.6% of total enrollment is foreign participation. Of the 27,044 participants, 50.5% were women, 49.5% were men and 0% did not provide sex identification. Further, 54.5% of the total participants in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (*See 2006 Report, Table 4 and Appendix Table 9A*)

Correspondingly, 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. (*Table 4 and* Appendix *Table 9A*)

There was a small increase in women (50.5% to 54.0%) and corresponding decrease in men (49.5% to 46.0%). The number of participants in Phase III intramural clinical research increased from 27,044 to 31,476.

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY1995 – FY2006

The following section is a new addition to the Annual Comprehensive report. Tables 5-11 provide trend data on the collection and reporting of human subject participation in NIH funded clinical research, which includes Phase III clinical studies; trend data are also provided in terms of foreign and domestic participation. 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 twelve 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 10,758 in FY2006 – a 3.4 fold increase. Reported enrollment increased from approximately 1.0 million (FY1995) to 14.8 million (FY2006) – a 14.5 fold increase; minority enrollment increased from approximately 0.4 million (FY2002) to 6.4 million (FY2006) – a 17.1 increase in minority representation in NIH clinical research. Over the last five years, the total number of protocols reported with enrollment data has leveled off at about 10,000 protocols per year.

With the deployment of a new population tracking system in 2002 and the 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 now available for domestic and foreign protocols and participation beginning in FY2002. Domestic enrollment increased from 10.2 million (FY2002) to 11.4 million (FY2006) – a 1.1 fold increase. Foreign enrollment increased from 0.9 million (FY2002) to 3.4 million (FY2006) – a 3.6 fold increase. Overall, the total enrollment has increased with domestic participation averaging between 75.9-91.5% and foreign participation averaging between 8.5-24.1%. In FY2006, domestic and foreign enrollment was 77.0% and 23.0% 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 34.9% and 45.0%. Overall minority participation in all extramural and intramural clinical research averaged between 31% and 43%. Table 6E provides a comparison of domestic and foreign participation between FY2002 and FY2006. 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 five-year period. Domestic minority enrollment varied between 24.1% and 28.9% of total domestic participation, while foreign minority enrollment varied between 82.2% 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 26.9% to 33.5%. Table 7E provides a comparison of domestic and foreign participation between FY2002 and FY2006. The vast majority of protocols are domestic (75.5% and 95.8%) of the total clinical research protocols. While the number of foreign protocols has decreased, they incorporate only about 4.2%-9.6% of the total clinical research protocols with enrollment in the last three years. Table 7F shows domestic and foreign enrollment for the five-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 85.2% of total foreign participation. Comparing both domestic and foreign Phase III enrollment over the five year period shows that the small percentage of foreign protocols (9.6%) in FY2006 account for a significant proportion (19.8%) of the total 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 61.8 and 67.3% while male participation averaged between 31.2 and 36.9%. (*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 64.6% 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 58.5% while male participation varied from 40.1% 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 56.7% while male participation varied from 42.0% to 52.5%. *(Table 11)*

Table 1. Summary of NIH Clinical Research Reported In FY2006: 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	10,758	10,294	95.7%	464	4.3%
%	70.2%	70.3%		69.3%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,562	4,356	95.5%	206	4.5%
	29.8%	29.7%		30.7%	
Total Number of Protocols	**15,320**	**14,650**	95.6%	**670**	4.4%
%	100.0%	100.0%		100.0%	

See Table 1A comments on next page.

1B. ENROLLMENT REPORTED	Total All Clinical Studies*	Domestic	%	Foreign	%
Females Enrolled	9,473,273	7,684,453	81.1%	1,788,820	18.9%
%	63.9%	67.3%		52.5%	
Males Enrolled	5,172,205	3,566,577	69.0%	1,605,628	31.0%
%	34.9%	31.2%		47.2%	
Sex of Subjects is Unknown	185,452	174,671	94.2%	10,781	5.8%
%	1.3%	1.5%		0.3%	
Total Subjects Enrolled	**14,830,930**	**11,425,701**	77.0%	**3,405,229**	23.0%
%	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**	**6,388,316**	**3,301,135**	51.7%	**3,087,181**	48.3%
% Minority Enrollment	**43.1%**	**28.9%**		90.7%	

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 1997U.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 FY2006: 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 FY2006 was 15,320; of these, 10,758 (70.2%) reported subject enrollment.

2. Subsequent Tables reporting "Enrollment Reported" are based on the 10,758 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 (14,650; 95.6%); of these, 10,294 (70.3%) reported domestic subject enrollment.

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

Table 1B: Total Enrollment Reported

1. The total "Enrollment Reported" in the NIH database in FY2006 was 14,830,930 subjects in 10,758 protocols with enrollment.

2. Females made up 63.9% (9.5M) of the total subjects enrolled, while Males made up 31.2%(5.2M), with 1.3% unknown.

Total Domestic Enrollment Reported

3. The total Domestic Enrollment reported was 11,425,701 (77%).

4. Females made up 67.3%(7.7M) of the domestic subjects enrolled, while Males made up 31.2%(3.56M), with1.5%(.17M) unknown.

Table 1C Comments: Minority Enrollment Reported

1. Minorities made up 43.1% (6.4M) of the total subjects enrolled.
2. Minorities made up 28.9%(3.3M) of the Domestic Enrollment.

3. The Total Minority Enrollment was made up of 51.7% Domestic and 48.3% Foreign enrollment The small percentage of foreign protocols (4.0%) account for a significant proportion (48.3%) of the total minority enrollment.

Table 2: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2006: 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		1,338	1,162	86.8%	124	9.3%	46	3.4%	6	0.4%
%		8.7%	9.0%		7.3%		8.1%		6.1%	
Number of Protocols reporting males only		581	468	80.6%	93	16.0%	17	2.9%	3	0.5%
%		3.8%	3.6%		5.5%		3.0%		3.0%	
Number of Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)		8,839	7,221	81.7%	1,226	13.9%	321	3.6%	71	0.8%
%		57.7%	55.8%		72.2%		56.2%		71.7%	
Total Number of Protocols with Enrollment		**10,758**	**8,851**	82.3%	**1,443**	13.4%	**384**	3.6%	**80**	0.7%
%		70.2%	68%		84.9%		67.3%		80.8%	
Number of Protocols with zero enrollment. Enrollment data has not yet been submitted.		4,562	4,100	89.9%	256	5.6%	187	4.1%	19	0.4%
%		29.8%	31.7%		15.1%		32.7%		19.2%	
Total Number of Protocols		**15,320**	**12,951**	84.5%	**1,699**	11.1%	**571**	3.7%	**99**	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		4,120,055	3,678,382	89.3%	202,024	4.9%	115,369	2.8%	124,280	3.0%
%		27.8%	36.9%		13.9%		3.8%		35.0%	
In Protocols reporting males only		336,717	274,774	81.6%	3,294	1.0%	32,552	9.7%	26,097	7.8%
%		2.3%	2.8%		0.2%		1.1%		7.3%	
In Protocols excluding female-only and male-only enrollment protocols		10,374,158	6,018,281	58.0%	1,248,946	12.0%	2,902,088	28.0%	204,843	2.0%
%		69.9%	60.4%		85.9%		95.2%		57.7%	
Enrollment Totals for all studies		**14,830,930**	**9,971,437**	67.2%	**1,454,264**	9.8%	**3,050,009**	20.6%	**355,220**	2.4%
%		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		**6,388,316**	**3,102,731**	48.6%	**198,404**	3.1%	**2,878,826**	45.1%	**208,355**	3.3%
% Minority enrollment		43.1%	31.1%		13.6%		94.4%		58.7%	

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.

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 1,338 protocols reporting females only, representing 12.4 %(1338/10,758) of protocols with enrollment.

90% were Extramural projects(1,162+46); 10% were NIH intramural projects(124+6).
96% were Domestic protocols(1162+124);4% were Foreign protocols(40+6).

2. Male Only Protocols: There were 581 protocols reporting males only, representing 5%(558/10,758) of protocols with enrollment.

83 % were Extramural projects(468+17); 17% were NIH intramural projects(93+3)
97% were Domestic protocols(468+93); 3 % were Foreign protocols(17+3).

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 8,839 protocols reporting both female and male participants representing 82%(8,839/10,758) of the total number of protocols.

85% were Extramural projects(7,221+321); 15% were NIH intramural projects(1,226+71)

Table 2B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 4.1 M females, representing 28% of total enrollment.

92.1% were in Extramural projects; 7.9% were in NIH intramural projects.
94.2% were in Domestic protocols; 5.8% were in Foreign protocols.

2. In Male Only Protocols: There were approximately 336,717 males, representing 2.3% of total enrollment.

91.3% were in Extramural projects; 18.8% were in NIH intramural projects.
82.6% were Domestic in protocols 17.4 % were Foreign protocols.

3. In Protocols Reporting Both Females and Males (excluding sex-specific studies): There were approximately 10,374,158 subjects, representing 70% of total enrollment.

86% were in Extramural projects;14% were in NIH intramural projects.
70% were in Domestic protocols; 30% were in Foreign protocols.
96% were Domestic protocols(7,221+1,226);4% were Foreign protocols(321+71).

Table 2C Minority Enrollment Reported

1. Total Minority Enrollment: 43.1% of Total Enrollment (14.8M).

Total Minority Enrollment, Domestic only: 28.9% (3,301,135/11,425,701)
Total Domestic Minority Enrollment: 51.7% (3,301,135/6,388,316)
Total Foreign Minority Enrollment: 48.3% (3,087,181/6,388,316)
Total Extramural projects Minority enrollment: 40.33% (5,981,557/14,830,930)
Total Intramural Projects Minority enrollment: 2.74% (406,759/14,830,930)

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2006: 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	624	564	90.4%	60	9.6%
%	82.1%	82.0%		83.3%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	136	124	91.2%	12	8.8%
	17.9%	18.0%		16.7%	
Total Number of Protocols	**760**	**688**	90.5%	**72**	9.5%
%	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	314,066	258,467	82.3%	55,599	17.7%
%	62.9%	64.6%		56.1%	
Males Enrolled	179,975	137,621	76.5%	42,354	23.5%
%	36.0%	34.4%		42.7%	
Sex of Subjects is Unknown	5,389	4,209	78.1%	1,180	0.0%
%	1.1%	1.1%		1.2%	
Total Subjects Enrolled	**499,430**	**400,297**	80.2%	**99,133**	19.8%
%	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	**167,446**	**83,034**	49.6%	**84,412**	50.4%
	33.5%	20.7%		85.2%	

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 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 3. Summary of NIH Phase III Clinical Research Reported In FY2006: 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 FY2006 was 760; of these, 624(82.1%) reported subject enrollment.
2. Subsequent Tables reporting "Enrollment Reported" are based on the 624 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 (688; 90.5%); of these 564(82%) reported domestic subject enrollment.
5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Table 3B Total Enrollment Reported

1. The total "Enrollment Reported" in NIH Defined Phase III Protocols in the NIH database in FY2006 was 499,430 subjects in 624 protocols.
2. Females made up 62.9% (314,068) of the total subjects enrolled, while Males made up 36.0%(179,975), with 1.1%(5,389) unknown.
3. Minorities made up 33.5% (167,446) of the total subjects enrolled.

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 400,297(80.2%).
5. Females made up 64.6%(258,467) of the domestic subjects enrolled, while Males made up 34.4%(137,621), with 1.1%(4,209) unknown.

Table 3C Minority Enrollment Reported

1. Minorities made up 33.5% of total subjects enrolled.
2. Minorities made up 20.7%(83,034) of the Domestic Enrollment (400,297).
3. The Total Minority Enrollment was made up of 49.6% Domestic and 50.4% Foreign enrollment.

Table 4. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2006: 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		118	101	85.6%	2	1.7%	14	11.9%	1	0.8%
%		15.5%	15.8%		4.2%		20.9%		20.0%	
Protocols reporting male only		47	39	83.0%	4	8.5%	4	8.5%	0	0.0%
%		6.2%	6.1%		8.3%		6.0%		0.0%	
Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)		459	384	83.7%	34	7.4%	38	8.3%	3	0.7%
%		60.4%	60.0%		70.8%		56.7%		60.0%	
Total Number of Protocols with Enrollment		**624**	**524**	84.0%	**40**	6.4%	**56**	9.0%	**4**	0.6%
%		82.1%	82%		83.3%		83.6%		80.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.		136	116	85.3%	8	5.9%	11	8.1%	1	0.0%
%		17.9%	18.1%		16.7%		16.4%		20.0%	
Total Number of Phase III Protocols		**760**	**640**	84.2%	**48**	6.3%	**67**	8.8%	**5**	0.7%
%		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		167,624	148,185	88.4%	4	0.0%	17,195	10.3%	2240	1.3%
%		33.6%	38.4%		0.0%		21.0%		13.0%	
Protocols reporting male only		27,723	23,312	84.1%	177	0.6%	4,234	15.3%	0	0.0%
%		5.6%	6.0%		1.2%		5.2%		0.0%	
Protocols excluding female-only and men-only enrollment protocols		304,083	214,619	70.6%	14,000	4.6%	60,409	19.9%	15,055	5.0%
%		60.9%	55.6%		98.7%		73.8%		87.0%	
Total Subjects Enrolled		**499,430**	**386,116**	77.3%	**14,181**	2.84%	**81,838**	16.39%	**17,295**	3.5%
%		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 studies		**167,446**	**80,622**	48.1%	**2,412**	1.4%	**69,820**	41.7%	**14,592**	8.7%
%		33.5%	20.9%		17.0%		85.3%		84.4%	

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.

COMMENTS

Table 4. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2006: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

Table 4A Total Number of Protocols with Enrollment

1. Female Only: There were 118 protocols reporting females only, representing 19 % (118/624) of protocols with enrollment, and 15.5% of the Total Number of Protocols.

97% were Extramural projects (115);3% were NIH intramural projects (3).
87% were Domestic protocols (103); 13% were Foreign protocols (15).

2. Male Only: There were 47 protocols reporting males only, representing 8% (47/624) of protocols with enrollment, and 6.2% of the Total Number of Protocols.

91% were Extramural projects (43); 9% were NIH intramural projects (4).
91% were Domestic protocols (43);9% were Foreign protocols (4).

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 459 protocols reporting both males and females representing 60.4 % of the total number of protocols.

92.0% were Extramural projects (422); 8.0% were NIH intramural projects (37).
91% were Domestic protocols (418); 9.0% were Foreign protocols (41).

Table 4B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 167,624 females, representing 33.6% of total enrollment.

98.7% (165,380) were in Extramural projects; 1.3% (2,244) were in NIH intramural projects.
88.4% (148,189) were in Domestic protocols; 11.67% (19,435) were in Foreign protocols.

2. In Male Only Protocols: There were approximately 27,723 males, representing 5.6% of total enrollment.

99.4% (27,546) were in Extramural projects; 0.6% (177) were in NIH intramural projects.
84.7% (23,489) were in Domestic protocols; 15.3% (4,234) were in Foreign protocols.

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were approximately 304,083 subjects, representing 60.9% of total enrollment.

90.45% (275,028) were in Extramural projects; 9.55% (29,055) were in NIH intramural projects.
75.2% (228,619) were in Domestic protocols; 24.8% (75,464) were in Foreign protocols.

Table 4C Minority Enrollment Reported

1. Total Minority Enrollment was 33.5% (167,446) of Total Enrollment (499,430).

Total Minority enrollment, *Extramural* protocols (150,442), was 30.12% of Total Enrollment (499,430) and 89.9% of Total Minority Enrollment (167,446).

Total Minority enrollment, *Intramural* Projects (17,004), was 3.4% of Total Enrollment (499,430) and 10.15% of Total Minority Enrollment (167,446).

2. Total Minority Enrollment, *Domestic only* (83,034), was 20.7% of total Domestic Enrollment (400,297) and 49.6% of Total Minority Enrollment (167,446).

3. Total Minority Enrollment, *Foreign* (84,412), was 85.15% of Total Foreign Enrollment (99,133) and 50.4% of Total Minority Enrollment (167,446).

Table 5. NIH Twelve Year Trends for Protocol and Enrollment Data: 1995-2006*

5A. Twelve Year Increases in Protocols and Enrollment Data			
FY Reported	**1995**	**2006**	**Relative Increase, 2006 / 1995**
Total Protocols with Enrollment	**3,188**	**10,758**	**3.4**
Total Enrollment	**1,021,493**	**14,830,930**	**14.5**
Total Minorities	**374,433**	**6,388,316**	**17.1**
% of Minority	**36.7%**	**43.1%**	**1.2**
FY Reported	**2002**	**2006**	**Relative Increase 2006 / 2002**
Total DOMESTIC Enrollment data	**10,192,401**	**11,425,701**	**1.1**
Total FOREIGN Enrollment	**946,083**	**3,405,229**	**3.6**

Table 5A Comments:

1. There was a 3.4 fold increase in protocols with enrollment reported from 1995 to 2006, from 3,188 protocols to 10,758 protocols.
2. There was a 14.5 fold increase in enrollment reported from 1995 to 2006, from approximately 1M to 15 M.
3. There was a 17.1 fold increase in minority enrollment from 1995 to 2006, from approximately 0.4 M to 6.4 M.
4. Domestic and Foreign data were reported for FY 2002-2006, and showed 1.1 fold increase in domestic enrollment (from 10.2M to 11.4M) and a 3.6 fold increase in foreign enrollment (from 0.95M to 3.4M).
5. See Table 6 for 12 year enrollment totals 1995-2006.

*NOTE: Trend data varies over time because the data for each year represent the net toal 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.

5B. Twelve Year Summary of Total Number of Protocols Reported: FY 1995-2006

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%	

Total Protocols by Year Reported

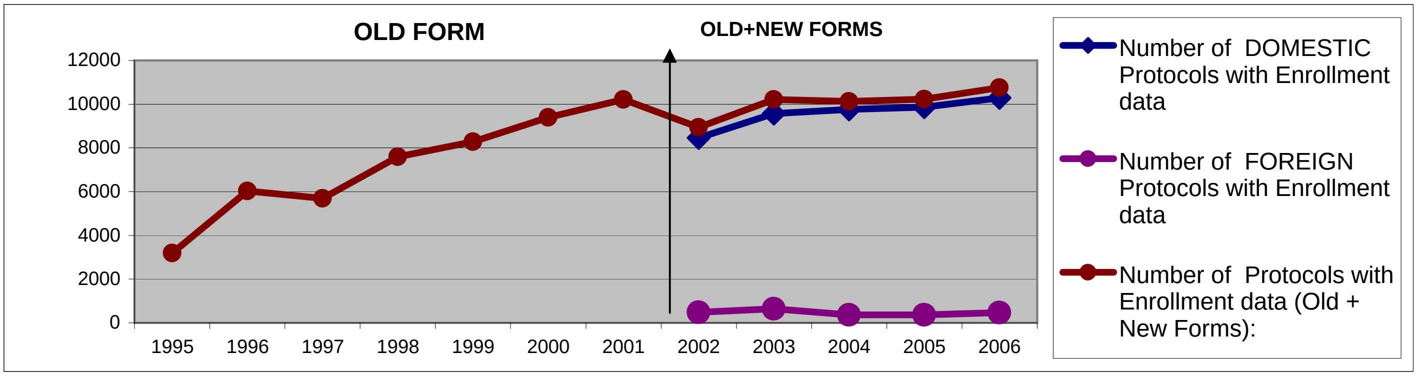


Table 5B Comments:

1. Table 5B and 5B Graph provide the number of OLD and NEW protocols year by year (1995-2006) and the distribution between domestic and foreign protocols for years 2002-2006.
2. The total number of protocols reported with enrollment have leveled off at about 15,000 over the last 4 years.

3. The vast majority of protocols were for domestic studies for 2002-2006, 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 2002-2006, 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.

5C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2006

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%

Percent Comparison of Domestic and Foreign Enrollment

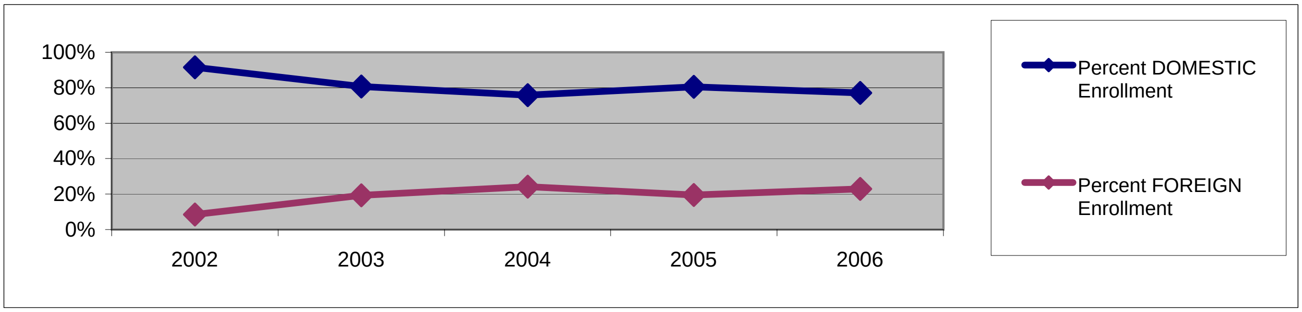


Table 5C Comments:

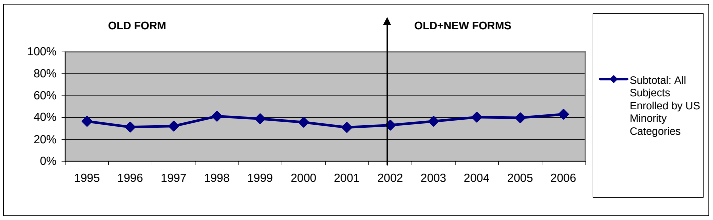
1. Overall total enrollment has increased, as well as total domestic and foreign enrollment during the last five years. The percentage of domestic enrollment has decreased to approximately 79% as the foreign enrollment has increased to approximately 21%.

Table 6. NIH Twelve Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2006: Enrollment by Race and Ethnicity

6A. TWELVE 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%	

Total Minority Enrollment by Year Reported



Sex/Gender Enrollment by Year Reported

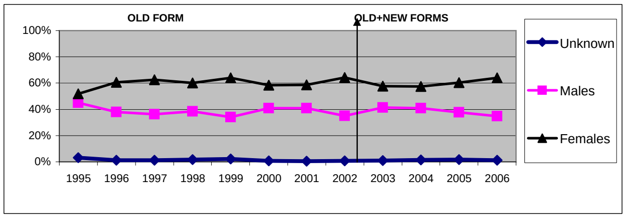


Table 6A Comments:

1. Table 6A summarizes enrollment by sex/gender and minority race/ethnicity categories for the twelve year reporting period (1995-2006). 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 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.

Table 6. NIH Twelve Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2006: 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%		

ORIENTATION TO TABLES 6C and 6D.

1. The New Form consists of Parts A and B (Tables 6C and 6D) for reporting years 2002-2006. 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%

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**	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%		

*** These totals must agree.**

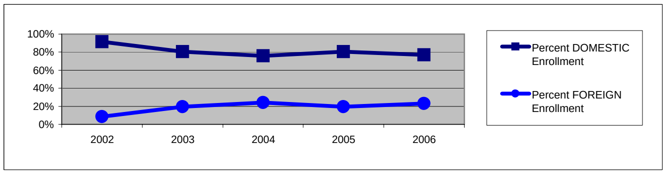
****These totals must agree.**

Table 6. NIH Twelve Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2006: Enrollment by Race and Ethnicity

6E. Comparison of Domestic and Foreign Enrollment & Protocols with Total Enrollment for the period FY2002-2006

		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%

Percentage of Domestic and Foreign Enrollment



Number of Domestic and Foreign protocols

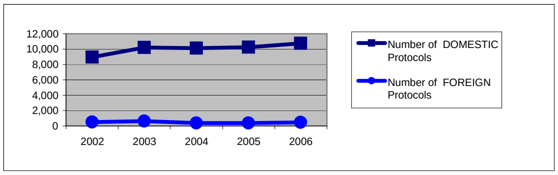


Table 6 E Comments:

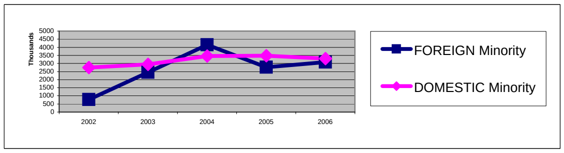
1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2006.
2. The Domestic enrollment decreased to approximately 80%, while the Foreign enrollment increased to approximately 20%.
3. The vast majority of protocols are domestic protocols (approximately 94-96%), while 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 2002-2006

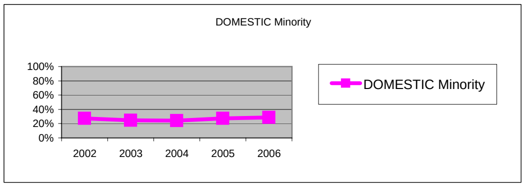
FY Reported	FY Funded	FOREIGN Minority	Foreign Total	DOMESTIC Minority	Domestic Total
2002	2001	777,461	946,083	2,754,820	10,149,869
		82.2%	100.0%	27.1%	100.0%
2003	2002	2,452,329	2,860,897	2,935,363	11,911,357
		85.7%	100.0%	24.6%	100.0%
2004	2003	4,147,255	4,564,127	3,464,356	14,359,793
		90.9%	100.0%	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%

NOTE MINORITY % WILL NOT ADD TO 100%

Number of Minority Participants for FY2002-2005



Percentage Comparison of Domestic Minority Enrollment to Total Domestic Enrollment for FY 2002-2006



Percentage Comparison of Foreign Minority Enrollment to Total Foreign Enrollment for FY 2002-2006

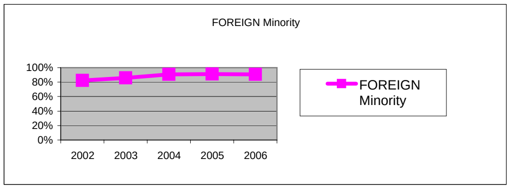


Table 6F Comments:

1. Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment.

research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary

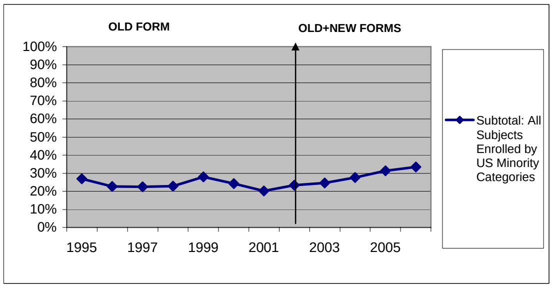
3. The Total Minority Enrollment reported in FY2006 was 52% Domestic and 48 % Foreign (see Table 1). The small percentage of foreign protocols account for a significant proportion (48%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

Table 7: Twelve Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2006: Enrollment by Race and Ethnicity

7A. Phase III TWELVE 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%	

Total Phase III Enrollment by Year Reported



Sex/Gender Phase III Enrollment by Year Reported

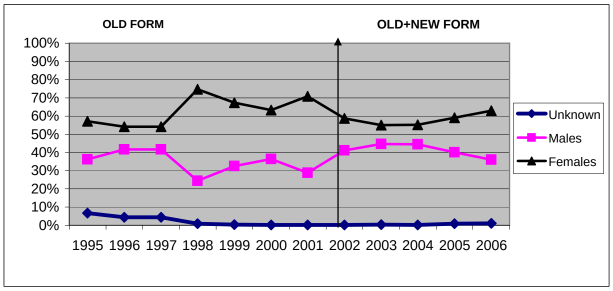


Table 7A Comments:

1. Table7A summarizes enrollment by sex/gender and minority race/ethnicity categories for the twelve year reporting period (1995-2006). 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.

Table 7: Twelve Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2006: 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%		

ORIENTATION TO TABLES 7C and 7D.

1. The New Form consists of Parts A and B (Tables 7C and 7D) for reporting years 2002-2006. 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%

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		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%		

*** These totals must agree**

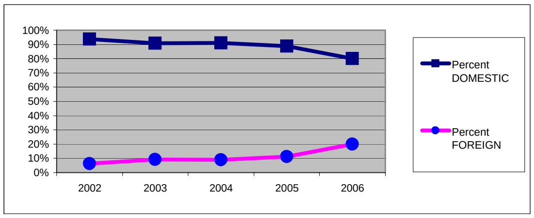
**** These totals must agree**

Table 7: Twelve Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2006: Enrollment by Race and Ethnicity

7E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2006

		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%

Percentage of Phase III Domestic and Foreign Enrollment



Number of Phase III Domestic and Foreign protocols

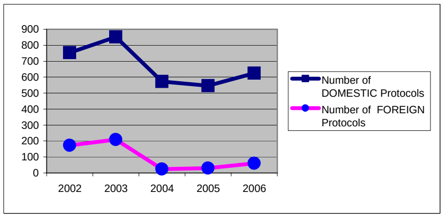


Table 7E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2006.
2. The Domestic enrollment decreased to approximately 80%, while the Foreign enrollment increased to approximately 20%.
3. The vast majority of protocols in FY2004-2006 are domestic protocols (approximately 90.4-95.8%), while foreign protocols make up approximately 4.2-9.6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

7F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2006

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%

Number of Minority Participants in Phase III Clinical Studies for FY2002-2006

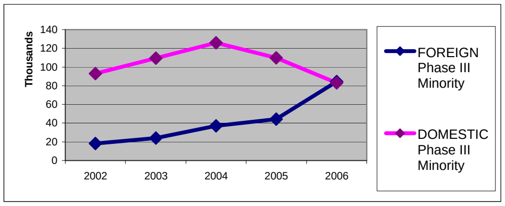


Table 7F Comments:

1. Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment.
2. Foreign Minority Enrollment has varied from 82.2% 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.
3. The Total Minority Enrollment reported in FY2006 was 52% Domestic and 48 % Foreign (see Table 1). The small percentage of foreign protocols account for a significant proportion (48%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

Table 8: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported: FY2002-2006: 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	Domestic Protocols with Enrollment data (Old +
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%	

Table 8A Comments:

1. There were approximately an average of 63% females, 35% males and 2% of unknown sex enrolled in domestic protocols from 2002-2006.
2. There were approximately an average of 27% domestic minority subjects enrolled in domestic protocols from 2002-2006.
3. Total domestic enrollment ranged from 10.1M to 11.5M during these 5 years.
4. The number of domestic protocols increased from 8,425 to 10,294 in 2006.

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).

Table 8: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2006: 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%		

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%

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 Form):
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%		

*** These totals must agree**

**** These totals must agree**

Table 9: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2006:Enrollment Using U.S. Race/Ethnicity

9A . Phase III 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**	**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%	

Table 9A Comments:

1. There were approximately an average of 57% females, 42% males and 0.3% of unknown sex enrolled in domestic protocols from 2002-2005.
2. There were approximately an average of 23.5% domestic minority subjects enrolled in domestic Phase III protocols from 2002-2006.
3. Total domestic Phase III enrollment ranged from 400,297to 496,241 during these 5 years.
4. The number of domestic Phase III protocols ranged from 517 to 564 in 2006.

Table 9: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2006: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%		

9C. 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	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%

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%		

*** These totals must agree**

**** These totals must agree**

Table 10. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2006: Enrollment Using U.S. Race/Ethnicity Categories

10A . FIVE 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%	

Table 10AComments:

1. The percent females varied from 39.2% to 58.5% in foreign protocols from 2002-2005; the percent males varied from 40.1% to 60.4%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in foreign protocols increased from 82.2% to 90.9% from 2002 to 2005.
3. Total foreign enrollment ranged from 777,461 to 4.15M during these 5 years.
4. The number of foreign protocols ranged from 638 in 2003 to 317 in 2005.

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

Table 10. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2006: 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%		

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%

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%		

*** These totals must agree**

**** These totals must agree**

Table 11. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2006: Enrollment Using U.S. Race/Ethnicity Categories

11A. Part A. Phase III FIVE 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%	

Table 11A Comments:

1. The percent females varied from 47.4% to 56.7% in Phase III foreign protocols from 2002-2006; the percent males varied from 42.0% to 52.5%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in Phase III foreign protocols increased from 60.4% to 85.2% from 2002 to 2006.
3. Total Phase III foreign enrollment increased from 30,311 to 99,133 during these 5 years.
4. The number of Phase III foreign protocols dropped from 209 in 2003 to 60 in 2006.

Table 11. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2006: 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%		

11C. 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**	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%	67.5%	0.0%	32.5%	100.0%
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%

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%		

*** 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).

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.

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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8. LaRosa, J. H., Seto, B., Caban, C.E., Hayunga, E.G., Including Women and Minorities in Clinical Research, *Applied Clinical Trials*, Vol. 4, No.5, p. 31-38, 1995.

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
Carlos Caban*, Viktoriya Anufriyeva, Maria Koshy, Peter Pruesch, Sam Shekar
Office of Acquisition, Management and Procurement
Barbara Levy

National Cancer Institute
Gail Blaufarb*, Marilyn Gaston, Kim Witherspoon, Lisa Krueger, Clarissa Douglass

National Eye Institute
Lore Anne McNicol*, William Darby, Pavi Miskala

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

National Human Genome Research Institute
Bettie Graham*, Pam Sellman

National Institute on Aging
Robin Barr *, Karen Bashir, Kate Nagy, Jamie Gulin

National Institute on Alcohol Abuse and Alcoholism
Dorita Sewell*, 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
Madeline Turkeltaub*, 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
Maria Canto*, Trenita Davis

National Institute of Diabetes, Digestive and Kidney Disorders
Patricia Robuck*, Christine Densmore, Lauren Meskill, Garman Williams

National Institute on Drug Addiction
Christie Baxter*

National Institute of Environmental Health Sciences
Martha Barnes *

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

National Institute of Mental Health
Catherine Roca *, Sue Kennel, Ernesto Marquez, Dawn Corbett, Kathleen O'Leary

National Institute of Neurological Disorders and Stroke
Frances Yee *, Kristy Woolbert, Aricia Ajose

National Institute of Nursing Research
Paul Cotton *, Christine Shaw

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

Warren G. Magnuson Clinical Center
Kim Jarema *, Dee Koziol

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*, Ivy Chan

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 YY; (b) the manner in which clinical trials are required to be designed and carried out YY; and (c) the operation of outreach programs YY 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.

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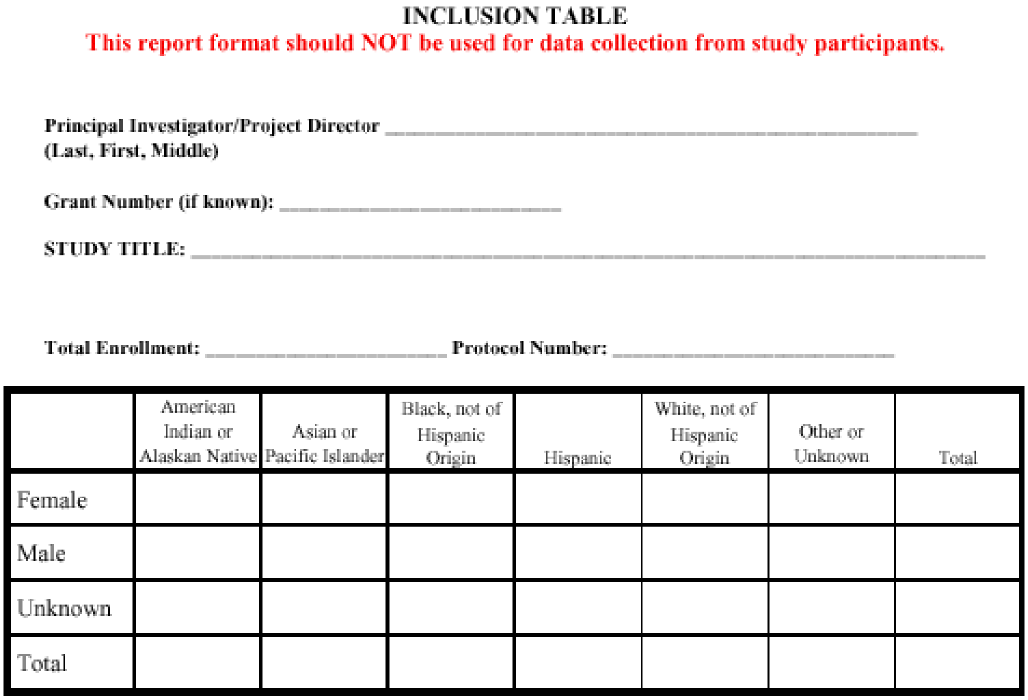
APPENDIX G

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



INCLUSION TABLE

This report format should NOT be used for data collection from study participants.

Principal Investigator/Project Director ___________________________________
(Last, First, Middle)

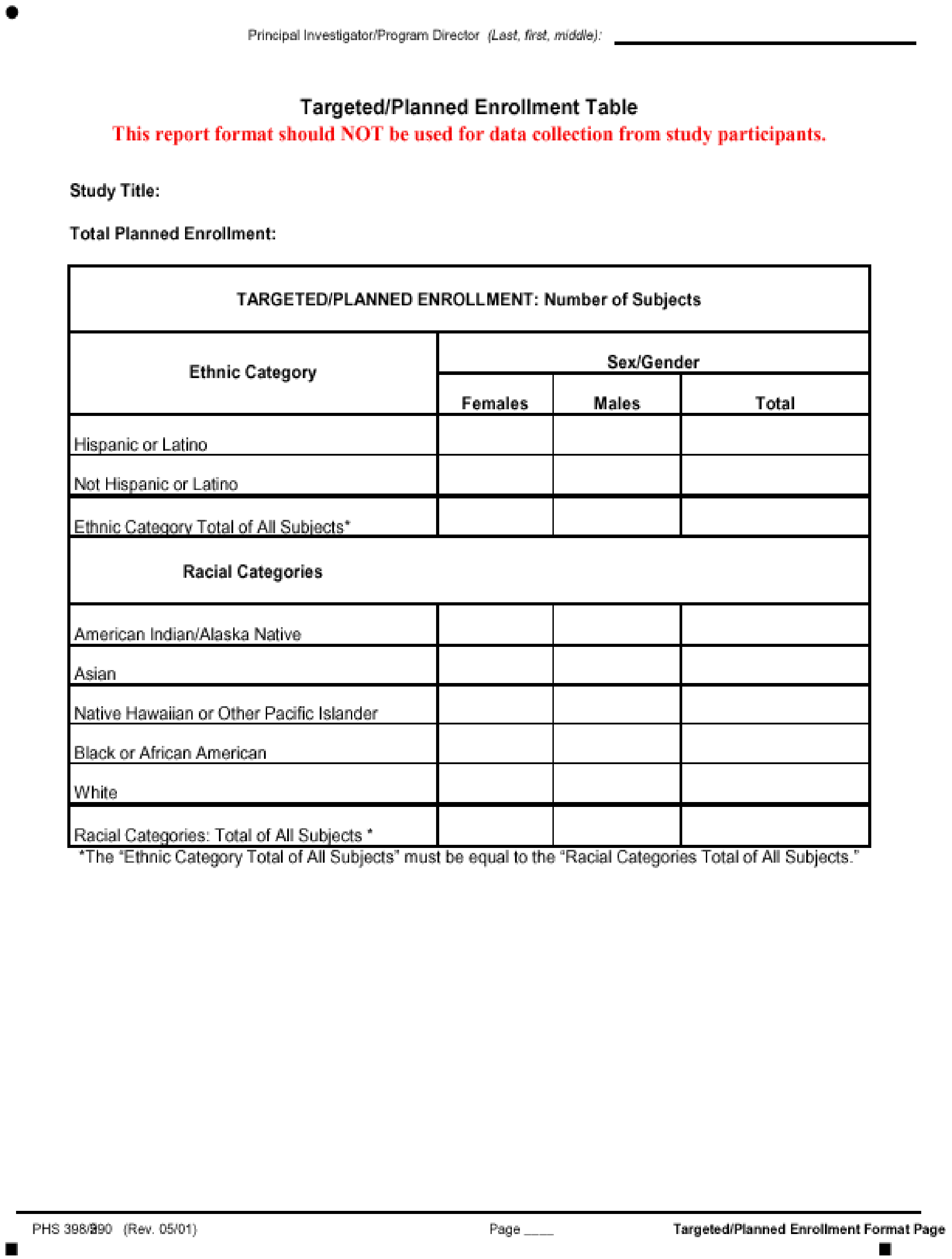
Grant Number (if known): ____________________

STUDY TITLE: ____

Total Enrollment: _________________ **Protocol Number:** ____________________

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

New Table for Target Data Collection



Principal Investigator/Program Director *(Last, first, middle)*: ____________________

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

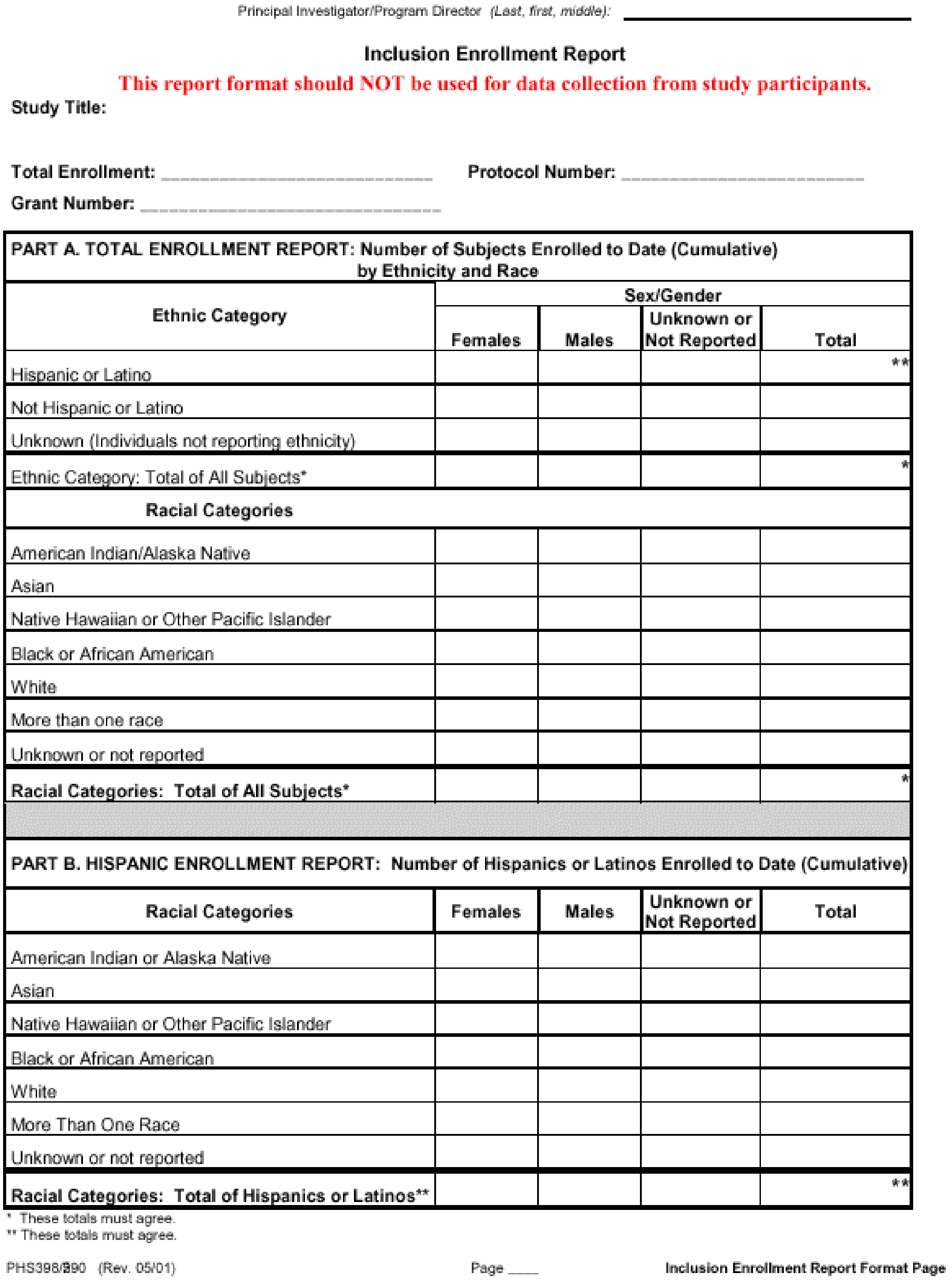
TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total of All Subjects*			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects *			

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

PHS 398/2590 (Rev. 05/01) Page ____ **Targeted/Planned Enrollment Format Page**

New Table for Enrollment Data Collection

-



Principal Investigator/Program Director *(Last, first, middle)*: ______________________

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:

Total Enrollment: ______________________ **Protocol Number:** ______________________

Grant Number: ______________________

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

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.

** These totals must agree.

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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 FY2005 and Reported in FY2006

Table of Contents: Fiscal Year 2006 Aggregate Data Tables

Domestic and Foreign Clinical Research Reported in FY 2005 and 2006

Table 1A. Aggregate Enrollment Data for Extramural and Intramural Research Funded in FY2005 and Reported in FY2006: Percent

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**9,473,273**	**3,818,620**		**40.31%**
%	**63.88%**	**59.78%**		
Males	**5,172,205**	**2,539,314**		**49.10%**
%	**34.87%**	**39.75%**		
Unknown	**185,452**	**30,382**		**16.38%**
%	**1.25%**	**0.48%**		
TOTAL	**14,830,930**	**6,388,316**	**43.07%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 10,758

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

Number of Protocols with Enrollment Data: 9,367

	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	95,866	1,945,321	822,173	22,825	4,822,122	178,585	765,876	8,652,768	7,301,261	676,197	675,310	8,652,768
	0.71%	**14.40%**	**6.09%**	**0.17%**	**35.70%**	**1.32%**	**5.67%**	**64.07%**	**54.06%**	**5.01%**	**5.00%**	**64.07%**
	1.11%	*22.48%*	*9.50%*	*0.26%*	*55.73%*	*2.06%*	*8.85%*	*100.00%*	*84.38%*	*7.81%*	*7.80%*	*100.00%*
	67.72%	56.17%	65.70%	59.35%	68.02%	55.54%	63.79%	64.07%	64.57%	64.14%	59.08%	64.07%
Male	44,963	1,513,810	418,413	15,568	2,221,924	139,053	334,142	4,687,873	3,945,254	369,120	373,499	4,687,873
	0.33%	**11.21%**	**3.10%**	**0.12%**	**16.45%**	**1.03%**	2.47%	**34.71%**	**29.21%**	**2.73%**	**2.77%**	**34.71%**
	0.96%	*32.29%*	*8.93%*	*0.33%*	*47.40%*	*2.97%*	7.13%	*100.00%*	*84.16%*	*7.87%*	*7.97%*	*100.00%*
	31.76%	43.71%	33.44%	40.48%	31.34%	43.24%	27.83%	34.71%	34.89%	35.01%	32.67%	34.71%
Unknown	738	4,071	10,753	67	44,971	3,916	100,523	165,039	61,730	8,995	94,314	165,039
	0.01%	**0.03%**	**0.08%**	0.00%	**0.33%**	**0.03%**	***0.74%***	**1.22%**	**0.46%**	**0.07%**	**0.70%**	**1.22%**
	0.45%	*2.47%*	*6.52%*	0.04%	*27.25%*	*2.37%*	*60.91%*	*100.00%*	*37.40%*	*5.45%*	*57.15%*	*100.00%*
	0.52%	0.12%	0.86%	0.17%	0.63%	1.22%	8.37%	1.22%	0.55%	0.85%	8.25%	1.22%
Total	141,567	3,463,202	1,251,339	38,460	7,089,017	321,554	1,200,541	13,505,680	11,308,245	1,054,312	1,143,123	13,505,680
	1.05%	**25.64%**	**9.27%**	**0.28%**	**52.49%**	**2.38%**	**8.89%**	**100.00%**	**83.73%**	**7.81%**	**8.46%**	**100.00%**
	1.05%	*25.64%*	*9.27%*	*0.28%*	*52.49%*	*2.38%*	*8.89%*	*100.00%*	*83.73%*	*7.81%*	*8.46%*	*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	24,676	4,469	12,781	1,262	295,420	96,288	241,301	676,197	3,601,491
	2.34%	**0.42%**	**1.21%**	**0.68%**	**28.02%**	**9.13%**	**22.89%**	**64.14%**	**26.67%**
	3.65%	*0.66%*	*1.89%*	*1.31%*	*43.69%*	*14.24%*	*35.69%*	*100.00%*	*41.62%*
	54.75%	67.29%	58.87%	57.55%	70.76%	51.91%	64.22%	64.14%	59.93%
Male	20,288	2,163	8,888	920	121,327	88,600	126,934	369,120	2,380,068
	1.92%	**0.21%**	**0.84%**	**0.50%**	**11.51%**	**8.40%**	**12.04%**	**35.01%**	**17.62%**
	5.50%	*0.59%*	*2.41%*	*1.04%*	*32.87%*	*24.00%*	*34.39%*	*100.00%*	*50.77%*
	45.01%	32.57%	40.94%	41.95%	29.06%	47.77%	33.78%	35.01%	39.61%
Unknown	110	9	43	11	748	588	7,486	8,995	27,779
	0.01%	**0.00%**	**0.00%**	**0.01%**	**0.07%**	**0.06%**	**0.71%**	**0.85%**	**0.21%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*16.83%*
	0.24%	0.14%	0.20%	0.50%	0.18%	0.32%	1.99%	0.85%	0.46%
TOTAL	45,074	6,641	21,712	2,193	417,495	185,476	375,721	1,054,312	6,009,338
	4.28%	**0.63%**	**2.06%**	**0.21%**	**39.60%**	**17.59%**	**35.64%**	**100.00%**	**44.49%**
	4.28%	*0.63%*	*2.06%*	*1.18%*	*39.60%*	*17.59%*	*35.64%*	*100.00%*	*44.49%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 1A

Number of Protocols with Enrollment Data: **1,391**

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	10,562	66,795	93,303	46,469	573,873	29,503	820,505	217,129
	0.80%	**5.04%**	**7.04%**	**3.51%**	**43.30%**	**2.23%**	**61.91%**	**16.38%**
	1.29%	*8.14%*	*11.37%*	*5.66%*	*69.94%*	*3.60%*	*100.00%*	*26.46%*
	53.76%	50.68%	62.64%	59.12%	64.99%	46.66%	61.91%	57.29%
Male	9,009	64,715	55,012	30,510	304,220	20,866	484,332	159,246
	0.68%	**4.88%**	**4.15%**	**2.30%**	**22.96%**	**1.57%**	**36.55%**	**12.02%**
	1.86%	*13.36%*	*11.36%*	*6.30%*	*62.81%*	*4.31%*	*100.00%*	*32.88%*
	45.85%	49.11%	36.93%	38.82%	34.45%	33.00%	36.55%	42.02%
Unknown	77	276	633	1,617	4,948	12,862	20,413	2603
	0.006%	**0.02%**	**0.05%**	**0.12%**	**0.37%**	**0.97%**	**1.54%**	**0.20%**
	0.38%	*1.35%*	*3.10%*	*7.92%*	*24.24%*	*63.01%*	*100.00%*	*12.75%*
	0.39%	0.21%	0.42%	2.06%	0.56%	20.34%	1.54%	0.69%
Total	19,648	131,786	148,948	78,596	883,041	63,231	1,325,250	378,978
	1.48%	**9.94%**	**11.24%**	**5.93%**	**66.63%**	**4.77%**	**100.00%**	**28.60%**
	1.48%	*9.94%*	*11.24%*	*5.93%*	*66.63%*	*4.77%*	*100.00%*	*28.60%*
	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 females (9,473,273 or 63.88%) than males (5,172,205 or 34.87%) are enrolled in aggregate extramural and intramural research protocols.

More minority females (3,818,620 or 59.78%) than minority males (2,539,314 or 39.75%) are enrolled in aggregate extramural and intramural research protocols.

Approximately 43.07% (6,388,316) of participants in aggregate extramural and intramural research (14,830,930) are classified as U.S. minorities.

Race:
Largest identified racial group is White at 66.63% following the 1977 OMB standards and 52.49% following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 11.24% following the 1977 OMB standards.
Largest identifiec racial minority group is Asians at 25.64% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 1.48%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.28%.

Ethnicity:
7.81% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is White at 39.6.25% (2nd hightest category is Unk/Other at 35.64%)
Smallest identified racial group is Hawaiian/Pacific islander at 0.21%
Of the 1,054,312 participants, 64.14% are women and 35% are men.
5.93% of participants identified as Hispanic according to the 1977 OMB standards.

Table 2A. Aggregate Enrollment Data for Extramural and Intramural Phase III Research Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	314,066	100,403		31.97%
%	62.88%	59.96%		
Males	179,975	66,450		36.92%
%	36.04%	39.68%		
Unknown	5,389	593		11.00%
%	1.08%	0.35%		
TOTAL	499,430	167,446	33.53%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 624

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

Number of Protocols with Enrollment Data: 409

	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	2,814	15,768	27,512	265	62,142	2,286	29,607	140,394	101,368	20,899	18,127	140,394
	1.04%	5.85%	10.20%	0.10%	23.04%	0.85%	10.98%	52.06%	37.59%	7.75%	6.72%	52.06%
	2.00%	11.23%	19.60%	0.19%	44.26%	1.63%	21.09%	100.00%	72.20%	14.89%	12.91%	100.00%
	60.78%	48.73%	54.18%	49.53%	49.06%	53.84%	58.69%	52.06%	50.09%	67.34%	49.97%	52.06%
Male	1,810	16,550	23,047	269	63,559	1,913	16,877	124,025	99,781	9,864	14,380	124,025
	0.67%	6.14%	8.55%	0.10%	23.57%	0.71%	6.26%	45.99%	37.00%	3.66%	5.33%	45.99%
	1.46%	13.34%	18.58%	0.22%	51.25%	1.54%	13.61%	100.00%	80.45%	7.95%	11.59%	100.00%
	39.09%	51.14%	45.39%	50.28%	50.18%	45.05%	33.46%	45.99%	49.31%	31.78%	39.64%	45.99%
Unknown	6	42	221	1	969	47	3,962	5,248	1,209	271	3,768	5,248
	0.00%	0.02%	0.08%	0.00%	0.36%	0.02%	1.47%	1.95%	0.45%	0.10%	1.40%	1.95%
	0.11%	0.80%	4.21%	0.02%	18.46%	0.90%	75.50%	100.00%	23.04%	5.16%	71.80%	100.00%
	0.13%	0.13%	0.44%	0.19%	0.76%	1.11%	7.85%	1.95%	0.60%	0.87%	10.39%	1.95%
Total	4,630	32,360	50,780	535	126,670	4,246	50,446	269,667	202,358	31,034	36,275	269,667
	1.72%	12.00%	18.83%	0.20%	46.97%	1.57%	18.71%	100.00%	75.04%	11.51%	13.45%	100.00%
	1.72%	12.00%	18.83%	0.20%	46.97%	1.57%	18.71%	100.00%	75.04%	11.51%	13.45%	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	1,384	31	370	28	4,378	382	14,326	20,899	67,349
	4.46%	0.10%	1.19%	3.93%	14.11%	1.23%	46.16%	67.34%	24.97%
	6.62%	0.15%	1.77%	7.33%	20.95%	1.83%	68.55%	100.00%	47.97%
	59.99%	62.00%	51.39%	70.00%	63.71%	53.58%	70.46%	67.34%	56.24%
Male	923	18	350	12	2,477	330	5,754	9,864	51,820
	2.97%	0.06%	1.13%	1.68%	7.98%	1.06%	18.54%	31.78%	19.22%
	9.36%	0.18%	3.55%	3.64%	25.11%	3.35%	58.33%	100.00%	41.78%
	40.01%	36.00%	48.61%	30.00%	36.04%	46.28%	28.30%	31.78%	43.27%
Unknown	0	1	0	0	17	1	252	271	586
	0.00%	0.00%	0.00%	0.00%	0.05%	0.00%	0.81%	0.87%	0.22%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	11.17%
	0.00%	2.00%	0.00%	0.00%	0.25%	0.14%	1.24%	0.87%	0.49%
TOTAL	2,307	50	720	40	6,872	713	20,332	31,034	119,755
	7.43%	0.16%	2.32%	0.13%	22.14%	2.30%	65.52%	100.00%	44.41%
	7.43%	0.16%	2.32%	5.61%	22.14%	2.30%	65.52%	100.00%	44.41%
	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: **215**

	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	775	9,626	15,860	6,793	136,836	3,782	173,672	33,054
	0.34%	**4.19%**	**6.90%**	**2.96%**	**59.56%**	**1.65%**	**75.59%**	**14.39%**
	0.45%	*5.54%*	*9.13%*	*3.91%*	*78.79%*	*2.18%*	*100.00%*	*19.03%*
	76.58%	57.30%	77.92%	71.33%	77.87%	59.58%	75.59%	69.31%
Male	237	7,172	4,490	2,731	38,864	2,456	55,950	14,630
	0.10%	**3.12%**	**1.95%**	**1.19%**	**16.91%**	**1.07%**	**24.35%**	**6.37%**
	0.42%	*12.82%*	*8.03%*	*4.88%*	*69.46%*	*4.39%*	*100.00%*	*26.15%*
	23.42%	42.69%	22.06%	28.67%	22.12%	38.69%	24.35%	30.68%
Unknown	0	2	5	0	24	110	141	7
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.05%**	**0.06%**	**0.00%**
	0.00%	*1.42%*	*3.55%*	*0.00%*	*17.02%*	*78.01%*	*100.00%*	*4.96%*
	0.00%	0.01%	0.02%	0.00%	0.01%	1.73%	0.06%	0.01%
Total	1,012	16,800	20,355	9,524	175,724	6,348	229,763	47,691
	0.44%	**7.31%**	**8.86%**	**4.15%**	**76.48%**	**2.76%**	**100.00%**	**20.76%**
	0.44%	*7.31%*	*8.86%*	*4.15%*	*76.48%*	*2.76%*	*100.00%*	*20.76%*
	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 females (314,066 or 62.88%) than males (179,975 or 36.04%) are enrolled in aggregate extramural and intramural Phase III research protocols.
More minority females (100,403 or 59.96%) than minority males (66,450 or 39.68%) are enrolled in aggregate extramural and intramural Phase III research protocols.

Approximately 33.53% (167,446) of participants in aggregate extramural and intramural Phase IIII research (499,430) are classified as U.S. minorities.

Race:
Largest identified racial group is White at 76.48% following the 1977 OMB standards and 46.97% following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 8.86% following the 1977 OMB standards.
Largest identifiec racial minority group is Black or African American at 18.83% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.44%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.20%.

Ethnicity:
11.51% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is Unknown at65.52% (2nd hightest category is White at 22.14%)
Smallest identified racial group is Asian at .016%
Of the 31,034 participants, 67.34% are women and 31.78% are men.
4.15% of participants identified as Hispanic according to the 1977 OMB standards.

Table 3A. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**8,470,418**	**3,551,143**		**41.92%**
%	**65.05%**	**59.37%**		
Males	**4,394,092**	**2,401,100**		**54.64%**
%	**33.75%**	**40.14%**		
Unknown	**156,936**	**29,314**		**18.68%**
%	**1.21%**	**0.49%**		
TOTAL	**13,021,446**	**5,981,557**	**45.94%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 9,235

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

Number of Protocols with Enrollment Data: **8,434**

	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	92,373	1,849,953	782,188	22,372	4,270,798	169,431	724,291	7,911,406	6,629,408	632,810	649,188	7,911,406
	0.76%	**15.22%**	**6.44%**	**0.18%**	**35.14%**	**1.39%**	**5.96%**	**65.09%**	**54.54%**	**5.21%**	**5.34%**	**65.09%**
	1.17%	*23.38%*	*9.89%*	*0.28%*	*53.98%*	*2.14%*	*9.16%*	*100.00%*	*83.80%*	*8.00%*	*8.21%*	*100.00%*
	67.84%	55.27%	66.05%	59.67%	70.94%	54.58%	64.69%	65.09%	65.80%	63.37%	60.07%	65.09%
Male	43,065	1,493,004	391,311	15,056	1,705,983	137,052	310,850	4,096,321	3,384,743	356,842	354,698	4,096,283
	0.35%	**12.28%**	**3.22%**	**0.12%**	**14.04%**	**1.13%**	2.56%	**33.70%**	**27.85%**	**2.94%**	**2.92%**	**33.70%**
	1.05%	*36.45%*	*9.55%*	*0.37%*	*41.65%*	*3.35%*	7.59%	*100.00%*	*82.63%*	*8.71%*	*8.66%*	*100.00%*
	31.63%	44.61%	33.04%	40.15%	28.34%	44.15%	27.76%	33.70%	33.59%	35.73%	32.82%	33.70%
Unknown	716	4,070	10,746	67	43,152	3,916	84,449	147,116	61,255	8,992	76,869	147,116
	0.01%	**0.03%**	**0.09%**	0.00%	**0.36%**	**0.03%**	***0.69%***	**1.21%**	**0.50%**	**0.07%**	**0.63%**	**1.21%**
	0.49%	*2.77%*	*7.30%*	0.05%	*29.33%*	*2.66%*	*57.40%*	*100.00%*	*41.64%*	*6.11%*	*52.25%*	*100.00%*
	0.53%	0.12%	0.91%	0.18%	0.72%	1.26%	7.54%	1.21%	0.61%	0.90%	7.11%	1.21%
Total	136,154	3,347,027	1,184,245	37,495	6,019,933	310,399	1,119,590	12,154,843	10,075,406	998,644	1,080,755	12,154,805
	1.12%	**27.54%**	**9.74%**	**0.31%**	**49.53%**	**2.55%**	**9.21%**	**100.00%**	**82.89%**	**8.22%**	**8.89%**	**100.00%**
	1.12%	*27.54%*	*9.74%*	*0.31%*	*49.53%*	*2.55%*	*9.21%*	*100.00%*	*82.89%*	*8.22%*	*8.89%*	*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	24,639	4,439	11,869	1,229	275,830	94,668	220,136	632,810	3,412,283
	2.47%	**0.44%**	**1.19%**	**0.67%**	**27.62%**	**9.48%**	**22.04%**	**63.37%**	**28.07%**
	3.89%	*0.70%*	*1.88%*	*1.30%*	*43.59%*	*14.96%*	*34.79%*	*100.00%*	*43.13%*
	54.74%	67.26%	59.32%	57.48%	69.75%	51.87%	63.46%	63.37%	59.26%
Male	20,261	2,152	8,097	898	118,879	87,266	119,289	356,842	2,317,656
	2.03%	**0.22%**	**0.81%**	**0.49%**	**11.90%**	**8.74%**	**11.95%**	**35.73%**	**19.07%**
	5.68%	*0.60%*	*2.27%*	*1.03%*	*33.31%*	*24.46%*	*33.43%*	*100.00%*	*56.58%*
	45.01%	32.61%	40.47%	42.00%	30.06%	47.81%	34.39%	35.73%	40.25%
Unknown	110	9	43	11	748	588	7,483	8,992	27,746
	0.01%	**0.00%**	**0.00%**	**0.01%**	**0.07%**	**0.06%**	**0.75%**	**0.90%**	**0.23%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*18.86%*
	0.24%	0.14%	0.21%	0.51%	0.19%	0.32%	2.16%	0.90%	0.48%
TOTAL	45,010	6,600	20,009	2,138	395,457	182,522	346,908	998,644	5,757,685
	4.51%	**0.66%**	**2.00%**	**0.21%**	**39.60%**	**18.28%**	**34.74%**	**100.00%**	**47.37%**
	4.51%	*0.66%*	*2.00%*	*1.17%*	*39.60%*	*18.28%*	*34.74%*	*100.00%*	*47.37%*
	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: **801**

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	2,643	24,769	73,843	37,605	398,749	21,403	559,012	138,860
	0.30%	**2.86%**	**8.52%**	**4.34%**	**46.01%**	**2.47%**	**64.51%**	**16.02%**
	0.47%	*4.43%*	*13.21%*	*6.73%*	*71.33%*	*3.83%*	*100.00%*	*24.84%*
	57.62%	61.06%	63.65%	59.96%	66.61%	48.51%	64.51%	62.03%
Male	1,867	15,560	41,532	24,485	197,293	17,034	297,771	83,444
	0.22%	**1.80%**	**4.79%**	**2.83%**	**22.77%**	**1.97%**	**34.36%**	**9.63%**
	0.63%	*5.23%*	*13.95%*	*8.22%*	*66.26%*	*5.72%*	*100.00%*	*28.02%*
	40.70%	38.36%	35.80%	39.04%	32.96%	38.61%	34.36%	37.27%
Unknown	77	236	632	623	2,568	5,684	9,820	1568
	0.009%	**0.03%**	**0.07%**	**0.07%**	**0.30%**	**0.66%**	**1.13%**	**0.18%**
	0.78%	*2.40%*	*6.44%*	*6.34%*	*26.15%*	*57.88%*	*100.00%*	*15.97%*
	1.68%	0.58%	0.54%	0.99%	0.43%	12.88%	1.13%	0.70%
Total	4,587	40,565	116,007	62,713	598,610	44,121	866,603	223,872
	0.53%	**4.68%**	**13.39%**	**7.24%**	**69.08%**	**5.09%**	**100.00%**	**25.83%**
	0.53%	*4.68%*	*13.39%*	*7.24%*	*69.08%*	*5.09%*	*100.00%*	*25.83%*
	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 females (8,470,418 or 65.05%) than males (4,394,092 or 33.75%) are enrolled in aggregate extramural research protocols.

More minority females (3,551,143 or 59.37%) than minority males (2,401,100 or 40.14%) are enrolled in aggregate extramural research protocols.

Approximately 45.94% (5,981,557) of participants in aggregate extramural research (13,021,446) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 69.08% following the 1977 OMB standards and 49.53% following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 13.39% following the 1977 OMB standards.
Largest identified racial minority group is Asian at 27.54% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.53%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.31%.

Ethnicity:

8.22% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
    Largest identified racial group is White at 39.6.25% (2nd hightest category is Unk/Other at 34.74%)
    Smallest identified racial group is Hawaiian/Pacific islander at 0.21%
    Of the 998,644 participants, 63.37% are women and 35.73% are men.
7.24% of participants identified as Hispanic according to the 1977 OMB standards.

Table 4A. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**4,676,672**	**2,470,214**		**52.82%**
%	**52.43%**	**51.75%**		
Males	**4,086,772**	**2,274,128**		**55.65%**
%	**45.81%**	**47.64%**		
Unknown	**156,925**	**29,314**		**18.68%**
%	**1.76%**	**0.61%**		
TOTAL	**8,920,369**	**4,773,656**	**53.51%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 7,542

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

Number of Protocols with Enrollment Data: 6,901

	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	50,404	1,427,672	453,526	18,831	1,955,114	150,208	288,636	4,344,391	3,754,525	386,779	203,087	4,344,391
	0.61%	**17.23%**	**5.47%**	**0.23%**	**23.59%**	**1.81%**	**3.48%**	**52.42%**	**45.30%**	**4.67%**	**2.45%**	**52.42%**
	1.16%	*32.86%*	*10.44%*	*0.43%*	*45.00%*	*3.46%*	*6.64%*	*100.00%*	*86.42%*	*8.90%*	*4.67%*	*100.00%*
	55.11%	50.26%	54.92%	55.70%	54.60%	52.11%	46.00%	52.42%	53.47%	52.10%	38.71%	52.42%
Male	40,338	1,408,865	361,574	14,907	1,582,618	134,112	254,321	3,796,735	3,205,404	346,625	244,668	3,796,697
	0.49%	**17.00%**	**4.36%**	**0.18%**	**19.09%**	**1.62%**	3.07%	**45.81%**	**38.67%**	**4.18%**	**2.95%**	**45.81%**
	1.06%	*37.11%*	*9.52%*	*0.39%*	*41.68%*	*3.53%*	6.70%	*100.00%*	*84.43%*	*9.13%*	*6.44%*	*100.00%*
	44.11%	49.60%	43.78%	44.10%	44.20%	46.53%	40.54%	45.81%	45.65%	46.69%	46.64%	45.81%
Unknown	716	4,070	10,746	67	43,152	3,916	84,449	147,116	61,255	8,992	76,869	147,116
	0.01%	**0.05%**	**0.13%**	0.00%	**0.52%**	**0.05%**	***1.02%***	**1.77%**	**0.74%**	**0.11%**	**0.93%**	**1.78%**
	0.49%	*2.77%*	*7.30%*	0.05%	*29.33%*	*2.66%*	*57.40%*	*100.00%*	*41.64%*	*6.11%*	*52.25%*	*100.00%*
	0.78%	0.14%	1.30%	0.20%	1.21%	1.36%	13.46%	1.77%	0.87%	1.21%	14.65%	1.78%
Total	91,458	2,840,607	825,846	33,805	3,580,884	288,236	627,406	8,288,242	7,021,184	742,396	524,624	8,288,204
	1.10%	**34.27%**	**9.96%**	**0.41%**	**43.20%**	**3.48%**	**7.57%**	**100.00%**	**84.71%**	**8.96%**	**6.33%**	**100.00%**
	1.10%	*34.27%*	*9.96%*	*0.41%*	*43.20%*	*3.48%*	*7.57%*	*100.00%*	*84.71%*	*8.96%*	*6.33%*	*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	20,614	2,031	8,715	946	120,586	87,921	145,966	386,779	2,367,193
	2.78%	**0.27%**	**1.17%**	**0.54%**	**16.24%**	**11.84%**	**19.66%**	**52.10%**	**28.56%**
	5.33%	*0.53%*	*2.25%*	*1.08%*	*31.18%*	*22.73%*	*37.74%*	*100.00%*	*54.49%*
	53.59%	48.73%	52.40%	51.22%	51.10%	50.39%	53.90%	52.10%	51.61%
Male	17,739	2,128	7,875	890	114,638	85,977	117,378	346,625	2,191,812
	2.39%	**0.29%**	**1.06%**	**0.51%**	**15.44%**	**11.58%**	**15.81%**	**46.69%**	**26.44%**
	5.12%	*0.61%*	*2.27%*	*1.04%*	*33.07%*	*24.80%*	*33.86%*	*100.00%*	*57.73%*
	46.12%	51.06%	47.35%	48.19%	48.58%	49.27%	43.34%	46.69%	47.79%
Unknown	110	9	43	11	748	588	7,483	8,992	27,746
	0.01%	**0.00%**	**0.01%**	**0.01%**	**0.10%**	**0.08%**	**1.01%**	**1.21%**	**0.33%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*18.86%*
	0.29%	0.22%	0.26%	0.60%	0.32%	0.34%	2.76%	1.21%	0.60%
TOTAL	38,463	4,168	16,633	1,847	235,972	174,486	270,827	742,396	4,586,751
	5.18%	**0.56%**	**2.24%**	**0.25%**	**31.79%**	**23.50%**	**36.48%**	**100.00%**	**55.34%**
	5.18%	*0.56%*	*2.24%*	*1.06%*	*31.79%*	*23.50%*	*36.48%*	*100.00%*	*55.34%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 4A

Number of Protocols with Enrollment Data: **641**

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	1,686	19,287	53,256	28,792	212,018	17,242	332,281	103,021
	0.27%	**3.05%**	**8.42%**	**4.55%**	**33.54%**	**2.73%**	**52.57%**	**16.30%**
	0.51%	*5.80%*	*16.03%*	*8.66%*	*63.81%*	*5.19%*	*100.00%*	*31.00%*
	46.70%	55.08%	56.34%	53.56%	52.17%	44.40%	52.57%	55.12%
Male	1,847	15,494	40,638	24,337	191,807	15,914	290,037	82,316
	0.29%	**2.45%**	**6.43%**	**3.85%**	**30.34%**	**2.52%**	**45.88%**	**13.02%**
	0.64%	*5.34%*	*14.01%*	*8.39%*	*66.13%*	*5.49%*	*100.00%*	*28.38%*
	51.16%	44.25%	42.99%	45.28%	47.20%	40.98%	45.88%	44.04%
Unknown	77	236	632	623	2,568	5,673	9,809	1568
	0.012%	**0.04%**	**0.10%**	**0.10%**	**0.41%**	**0.90%**	**1.55%**	**0.25%**
	0.78%	*2.41%*	*6.44%*	*6.35%*	*26.18%*	*57.83%*	*100.00%*	*15.99%*
	2.13%	0.67%	0.67%	1.16%	0.63%	14.61%	1.55%	0.84%
Total	3,610	35,017	94,526	53,752	406,393	38,829	632,127	186,905
	0.57%	**5.54%**	**14.95%**	**8.50%**	**64.29%**	**6.14%**	**100.00%**	**29.57%**
	0.57%	*5.54%*	*14.95%*	*8.50%*	*64.29%*	*6.14%*	*100.00%*	*29.57%*
	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: Reference Table 2A

Sex/Gender:

There were 9,235 protocols of which 1,208 (13.1%) were *female-only* protocols and 485 (5.25%) were *male-only* protocols.
Excluding sex-specific studies, the number of females (4,676,672 or 52.43%) exceeds the number of males (4,086,772 or 45.8%) enrolled in extramural research protocols.
Excluding sex-specific studies, the number of minority females (2,470,214 or 51.75%) exceeds the number of males (2,274,128 or 47.64%) enrolled in extramural research protocols.

Approximately 53.5% (4,773,656) of participants in aggregate extramural research excluding sex-specific studies (8,920,369) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 43.2% following the 1997 OMB standards and 64.3% following the 1977 OMB standards.
Largest identified racial minority group is Asian at 34.3% following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 14.95% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.4%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.57%.

Ethnicity:

8.96% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
    Largest identified racial group is Unknown at 36.5% (2nd hightest category is White at 31.79%)
    Smallest identified racial group is Hawaiian/Pacific Islander at 0.25%
    Of the 742,396 participants, 52.1% are women and 46.7% are men.
8.5% of participants identified as Hispanic according to the 1977 OMB standards.

Table 5A. Aggregate Enrollment Data for Extramural PhaseIII Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	297,077	90,794		30.56%
%	63.48%	60.35%		
Males	165,488	59,055		35.69%
%	35.36%	39.25%		
Unknown	5,389	593		11.00%
%	1.15%	0.39%		
TOTAL	467,954	150,442	32.15%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	580

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

Number of Protocols with Enrollment Data: 382

	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	2,806	15,679	27,019	264	56,963	2,021	25,881	130,633	95,599	18,373	16,661	130,633
	1.11%	**6.18%**	**10.64%**	**0.10%**	**22.44%**	**0.80%**	**10.20%**	**51.46%**	**37.66%**	**7.24%**	**6.56%**	**51.46%**
	2.15%	*12.00%*	*20.68%*	*0.20%*	*43.61%*	*1.55%*	*19.81%*	*100.00%*	*73.18%*	*14.06%*	*12.75%*	*100.00%*
	60.87%	48.75%	54.02%	49.44%	48.44%	53.64%	57.32%	51.46%	49.71%	64.96%	50.11%	51.46%
Male	1,798	16,443	22,778	269	59,657	1,700	15,309	117,954	95,493	9,641	12,820	117,954
	0.71%	**6.48%**	**8.97%**	**0.11%**	**23.50%**	**0.67%**	6.03%	**46.47%**	**37.62%**	**3.80%**	**5.05%**	**46.47%**
	1.52%	*13.94%*	*19.31%*	*0.23%*	*50.58%*	*1.44%*	12.98%	*100.00%*	*80.96%*	*8.17%*	*10.87%*	*100.00%*
	39.00%	51.12%	45.54%	50.37%	50.73%	45.12%	33.91%	46.47%	49.66%	34.09%	38.56%	46.47%
Unknown	6	42	221	1	969	47	3,962	5,248	1,209	271	3,768	5,248
	0.00%	**0.02%**	**0.09%**	0.00%	**0.38%**	**0.02%**	*1.56%*	**2.07%**	**0.48%**	**0.11%**	**1.48%**	**2.07%**
	0.11%	*0.80%*	*4.21%*	0.02%	*18.46%*	*0.90%*	*75.50%*	*100.00%*	*23.04%*	*5.16%*	*71.80%*	*100.00%*
	0.13%	0.13%	0.44%	0.19%	0.82%	1.25%	8.77%	2.07%	0.63%	0.96%	11.33%	2.07%
Total	4,610	32,164	50,018	534	117,589	3,768	45,152	253,835	192,301	28,285	33,249	253,835
	1.82%	**12.67%**	**19.70%**	**0.21%**	**46.32%**	**1.48%**	**17.79%**	**100.00%**	**75.76%**	**11.14%**	**13.10%**	**100.00%**
	1.82%	*12.67%*	*19.70%*	*0.21%*	*46.32%*	*1.48%*	*17.79%*	*100.00%*	*75.76%*	*11.14%*	*13.10%*	*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	1,384	31	370	28	4,378	382	11,800	18,373	63,967
	4.89%	**0.11%**	**1.31%**	**0.10%**	**15.48%**	**1.35%**	**41.72%**	**64.96%**	**25.20%**
	7.53%	*0.17%*	*2.01%*	*7.33%*	*23.83%*	*2.08%*	*64.22%*	*100.00%*	*48.97%*
	59.99%	62.00%	51.39%	70.00%	63.71%	53.58%	67.11%	64.96%	55.36%
Male	923	18	350	12	2,477	330	5,531	9,641	50,996
	3.26%	**0.06%**	**1.24%**	**1.68%**	**8.76%**	**1.17%**	**19.55%**	**34.09%**	**20.09%**
	9.57%	*0.19%*	*3.63%*	*3.64%*	*25.69%*	*3.42%*	*57.37%*	*100.00%*	*43.23%*
	40.01%	36.00%	48.61%	30.00%	36.04%	46.28%	31.46%	34.09%	44.13%
Unknown	0	1	0	0	17	1	252	271	586
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.06%**	**0.00%**	**0.89%**	**0.96%**	**0.23%**
	0.00%	*0.37%*	*0.00%*	*0.00%*	*6.27%*	*0.37%*	*92.99%*	*0.00%*	*11.17%*
	0.00%	2.00%	0.00%	0.00%	0.25%	0.14%	1.43%	0.96%	0.51%
TOTAL	2,307	50	720	40	6,872	713	17,583	28,285	115,549
	8.16%	**0.18%**	**2.55%**	**0.14%**	**24.30%**	**2.52%**	**62.16%**	**100.00%**	**45.52%**
	8.16%	*0.18%*	*2.55%*	*5.61%*	*24.30%*	*2.52%*	*62.16%*	*100.00%*	*45.52%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 5A

Number of Protocols with Enrollment Data: 198

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	649	3,633	15,783	6,762	135,840	3,777	166,444	26,827
	0.30%	**1.70%**	**7.37%**	**3.16%**	**63.44%**	**1.76%**	**77.73%**	**12.53%**
	0.39%	*2.18%*	*9.48%*	*4.06%*	*81.61%*	*2.27%*	*100.00%*	*16.12%*
	77.63%	80.99%	78.41%	71.61%	78.57%	59.65%	77.73%	76.88%
Male	187	851	4,340	2,681	37,030	2,445	47,534	8,059
	0.09%	**0.40%**	**2.03%**	**1.25%**	**17.29%**	**1.14%**	**22.20%**	**3.76%**
	0.39%	*1.79%*	*9.13%*	*5.64%*	*77.90%*	*5.14%*	*100.00%*	*16.95%*
	22.37%	18.97%	21.56%	28.39%	21.42%	38.61%	22.20%	23.10%
Unknown	0	2	5	0	24	110	141	7
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.05%**	**0.07%**	**0.00%**
	0.00%	*1.42%*	*3.55%*	*0.00%*	*17.02%*	*78.01%*	*100.00%*	*4.96%*
	0.00%	0.04%	0.02%	0.00%	0.01%	1.74%	0.07%	0.02%
Total	836	4,486	20,128	9,443	172,894	6,332	214,119	34,893
	0.39%	**2.10%**	**9.40%**	**4.41%**	**80.75%**	**2.96%**	**100.00%**	**16.30%**
	0.39%	*2.10%*	*9.40%*	*4.41%*	*80.75%*	*2.96%*	*100.00%*	*16.30%*
	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 (297,077 or 63.5%) than males (165,488 or 35.36%) are enrolled in aggregate Phase III Extramural research protocols.
More minority females (90,794 or 60.35%) than minority males (59,055 or 39.25%) are enrolled in aggregate PhaseIII Extramural research protocols.

Approximately 32.15% (150,442) of participants in aggregate Phase III Extramural research (467,954) are classified as U.S. minorities.

Race: White doesn't rank as a top racial category.
Largest identified racial minority group is Black or African American at 19.7% following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 19.4% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.21%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/ Alaska Native at 0.4%.

Ethnicity:
11.14% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
  Largest identified racial group is Unknown at 62.16% (2nd hightest category is White at 24.3%)
  Smallest identified racial group is Hawaiian/Pacific Islander at 0.14%.
  Of the 28,285 participants, 64.96% are women and 34.1% are men.
4.41% of participants identified 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 FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**131,697**	**48,873**		**37.11%**
%	**47.88%**	**47.78%**		
Males	**137,942**	**52,832**		**38.30%**
%	**50.16%**	**51.65%**		
Unknown	**5,389**	**593**		**11.00%**
%	**1.96%**	**0.58%**		
TOTAL	**275,028**	**102,298**	**37.20%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**422**

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

Number of Protocols with Enrollment Data: **288**

	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	2,377	11,417	19,578	180	35,842	1,271	17,427	88,092	64,267	7,953	15,872	88,092
	1.25%	**6.01%**	**10.31%**	**0.09%**	**18.88%**	**0.67%**	**9.18%**	**46.40%**	**33.85%**	**4.19%**	**8.36%**	**46.40%**
	2.70%	*12.96%*	*22.22%*	*0.20%*	*40.69%*	*1.44%*	*19.78%*	*100.00%*	*72.95%*	*9.03%*	*18.02%*	*100.00%*
	57.29%	42.13%	50.55%	40.18%	44.44%	43.29%	48.64%	46.40%	45.75%	46.02%	49.47%	46.40%
Male	1,766	15,640	18,931	267	43,846	1,618	14,442	96,510	75,008	9,056	12,446	96,510
	0.93%	**8.24%**	**9.97%**	**0.14%**	**23.10%**	**0.85%**	7.61%	**50.83%**	**39.51%**	**4.77%**	**6.56%**	**50.83%**
	1.83%	*16.21%*	*19.62%*	*0.28%*	*45.43%*	*1.68%*	14.96%	*100.00%*	*77.72%*	*9.38%*	*12.90%*	*100.00%*
	42.56%	57.71%	48.88%	59.60%	54.36%	55.11%	40.31%	50.83%	53.39%	52.41%	38.79%	50.83%
Unknown	6	42	221	1	969	47	3,962	5,248	1,209	271	3,768	5,248
	0.00%	**0.02%**	**0.12%**	0.00%	**0.51%**	**0.02%**	***2.09%***	**2.76%**	**0.64%**	**0.14%**	**1.98%**	**2.76%**
	0.11%	*0.80%*	*4.21%*	0.02%	*18.46%*	*0.90%*	*75.50%*	*100.00%*	*23.04%*	*5.16%*	*71.80%*	*100.00%*
	0.14%	0.15%	0.57%	0.22%	1.20%	1.60%	11.06%	2.76%	0.86%	1.57%	11.74%	2.76%
Total	4,149	27,099	38,730	448	80,657	2,936	35,831	189,850	140,484	17,280	32,086	189,850
	2.19%	**14.27%**	**20.40%**	**0.24%**	**42.48%**	**1.55%**	**18.87%**	**100.00%**	**74.00%**	**9.10%**	**16.90%**	**100.00%**
	2.19%	*14.27%*	*20.40%*	*0.24%*	*42.48%*	*1.55%*	*18.87%*	*100.00%*	*74.00%*	*9.10%*	*16.90%*	*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	1087	14	247	14	2,070	191	4,330	7,953	41,223
	6.29%	**0.08%**	**1.43%**	**2.72%**	**11.98%**	**1.11%**	**25.06%**	**46.02%**	**21.71%**
	13.67%	*0.18%*	*3.11%*	*7.33%*	*26.03%*	*2.40%*	*54.44%*	*100.00%*	*46.80%*
	54.30%	43.75%	42.81%	53.85%	46.74%	37.16%	44.64%	46.02%	47.12%
Male	915	17	330	12	2,342	322	5,118	9,056	45,682
	5.30%	**0.10%**	**1.91%**	**2.33%**	**13.55%**	**1.86%**	**29.62%**	**52.41%**	**24.06%**
	10.10%	*0.19%*	*3.64%*	*3.73%*	*25.86%*	*3.56%*	*56.52%*	*100.00%*	*47.33%*
	45.70%	53.13%	57.19%	46.15%	52.88%	62.65%	52.76%	52.41%	52.21%
Unknown	0	1	0	0	17	1	252	271	586
	0.00%	**0.01%**	**0.00%**	**0.00%**	**0.10%**	**0.01%**	**1.46%**	**1.57%**	**0.31%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*11.17%*
	0.00%	3.13%	0.00%	0.00%	0.38%	0.19%	2.60%	1.57%	0.67%
TOTAL	2,002	32	577	26	4,429	514	9,700	17,280	87,491
	11.59%	**0.19%**	**3.34%**	**0.15%**	**25.63%**	**2.97%**	**56.13%**	**100.00%**	**46.08%**
	11.59%	*0.19%*	*3.34%*	*5.06%*	*25.63%*	*2.97%*	*56.13%*	*100.00%*	*46.08%*
	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: **134**

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	167	919	4,172	2,392	34,784	1,171	43,605	7,650
	0.20%	**1.08%**	**4.90%**	**2.81%**	**40.84%**	**1.37%**	**51.19%**	**8.98%**
	0.38%	*2.11%*	*9.57%*	*5.49%*	*79.77%*	*2.69%*	*100.00%*	*17.54%*
	49.26%	53.46%	53.51%	48.30%	51.34%	44.64%	51.19%	51.66%
Male	172	798	3,620	2,560	32,940	1,342	41,432	7,150
	0.20%	**0.94%**	**4.25%**	**3.01%**	**38.67%**	**1.58%**	**48.64%**	**8.39%**
	0.42%	*1.93%*	*8.74%*	*6.18%*	*79.50%*	*3.24%*	*100.00%*	*17.26%*
	50.74%	46.42%	46.43%	51.70%	48.62%	51.16%	48.64%	48.29%
Unknown	0	2	5	0	24	110	141	7
	0.000%	**0.00%**	**0.01%**	**0.00%**	**0.03%**	**0.13%**	**0.17%**	**0.01%**
	0.00%	*1.42%*	*3.55%*	*0.00%*	*17.02%*	*78.01%*	*100.00%*	*4.96%*
	0.00%	0.12%	0.06%	0.00%	0.04%	4.19%	0.17%	0.05%
Total	339	1,719	7,797	4,952	67,748	2,623	85,178	14,807
	0.40%	**2.02%**	**9.15%**	**5.81%**	**79.54%**	**3.08%**	**100.00%**	**17.38%**
	0.40%	*2.02%*	*9.15%*	*5.81%*	*79.54%*	*3.08%*	*100.00%*	*17.38%*
	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: Reference Table 4A

Sex/Gender:

There were 580 PhaseIII Extramural protocols of which 115 (19.8%) were *female-only* protocols and 43 (7.4%) were *male-only* protocols.

Excluding sex-specific studies, the number of males (137,942 or 50.16%) exceeds the number of females (131,697 or 47.88%) enrolled in Phase III Extramural research protocols.

Excluding sex-specific studies, the number of minority males (52,832 or 51.65%) exceeds the number of females (48,873 or 47.78%) enrolled in Phase III Extramural research protocols.

Approximately 37.2% (102.298) of participants in aggregate Phase III Extramural research excluding sex-specific studies (275,028) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 42.5% following the 1997 OMB standards and 79.54% following the 1977 OMB standards.

Largest identified racial minority group is Black at 20.4% following the 1997 OMB standards.

Largest identified racial minority group is Black or African American at 9.15% following the 1997 OMB standards.

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.24%.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.4%.

Ethnicity:

9.1% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.

For participants reporting ethcnicity as Hispanic/Latino:

Largest identified racial group is Unknown at 56.13 % (2nd hightest category is White at 25.63%)
Smallest identified racial group is Hawaiian/Pacific Islander at 0.15%
Of the 17,280 participants, 52.4% are men and 46.02% are women.

5.8% of participants identified as Hispanic according to the 1977 OMB standards.

Table 7A. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**1,002,855**	**267,477**		**26.67%**
%	**55.42%**	**65.76%**		
Males	**778,113**	**138,214**		**17.76%**
%	**43.00%**	**33.98%**		
Unknown	**28,516**	**1,068**		**3.75%**
%	**1.58%**	**0.26%**		
TOTAL	**1,809,484**	**406,759**	**22.48%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	1,523

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

Number of Protocols with Enrollment Data: 933

	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	3,493	95,368	39,985	453	551,324	9,154	41,585	741,362	671,853	43,387	26,122	741,362
	0.26%	**7.06%**	**2.96%**	**0.03%**	**40.81%**	**0.68%**	**3.08%**	**54.88%**	**49.74%**	**3.21%**	**1.93%**	**54.88%**
	0.47%	*12.86%*	*5.39%*	*0.06%*	*74.37%*	*1.23%*	*5.61%*	*100.00%*	*90.62%*	*5.85%*	*3.52%*	*100.00%*
	64.53%	82.09%	59.60%	46.94%	51.57%	82.06%	51.37%	54.88%	54.50%	77.94%	41.91%	54.88%
Male	1,898	20,806	27,102	512	515,941	2,001	23,292	591,552	560,511	12,278	18,763	591,552
	0.14%	**1.54%**	**2.01%**	**0.04%**	**38.19%**	**0.15%**	1.72%	**43.79%**	**41.49%**	**0.91%**	**1.39%**	**43.79%**
	0.32%	*3.52%*	*4.58%*	*0.09%*	*87.22%*	*0.34%*	3.94%	*100.00%*	*94.75%*	*2.08%*	*3.17%*	*100.00%*
	35.06%	17.91%	40.39%	53.06%	48.26%	17.94%	28.77%	43.79%	45.47%	22.06%	30.10%	43.79%
Unknown	22	1	7	0	1,819	0	16,074	17,923	475	3	17,445	17,923
	0.00%	**0.00%**	**0.00%**	0.00%	**0.13%**	**0.00%**	***1.19%***	**1.33%**	**0.04%**	**0.00%**	**1.29%**	**1.33%**
	0.12%	*0.01%*	*0.04%*	0.00%	*10.15%*	*0.00%*	*89.68%*	*100.00%*	*2.65%*	*0.02%*	*97.33%*	*100.00%*
	0.41%	0.00%	0.01%	0.00%	0.17%	0.00%	19.86%	1.33%	0.04%	0.01%	27.99%	1.33%
Total	5,413	116,175	67,094	965	1,069,084	11,155	80,951	1,350,837	1,232,839	55,668	62,330	1,350,837
	0.40%	**8.60%**	**4.97%**	**0.07%**	**79.14%**	**0.83%**	**5.99%**	**100.00%**	**91.26%**	**4.12%**	**4.61%**	**100.00%**
	0.40%	*8.60%*	*4.97%*	*0.07%*	*79.14%*	*0.83%*	*5.99%*	*100.00%*	*91.26%*	*4.12%*	*4.61%*	*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	37	30	912	33	19,590	1,620	21,165	43,387	189,208
	0.07%	**0.05%**	**1.64%**	**1.12%**	**35.19%**	**2.91%**	**38.02%**	**77.94%**	**14.01%**
	0.09%	*0.07%*	*2.10%*	*2.04%*	*45.15%*	*3.73%*	*48.78%*	*100.00%*	*25.52%*
	0.00%	0.00%	0.00%	0.00%	0.00%	54.84%	73.46%	77.94%	75.19%
Male	27	11	791	22	2,448	1,334	7,645	12,278	62,412
	0.05%	**0.02%**	**1.42%**	**0.74%**	**4.40%**	**2.40%**	**13.73%**	**22.06%**	**4.62%**
	0.22%	*0.09%*	*6.44%*	*1.65%*	*19.94%*	*10.86%*	*62.27%*	*100.00%*	*10.55%*
	0.00%	0.00%	0.00%	0.00%	0.00%	45.16%	26.53%	22.06%	24.80%
Unknown	0	0	0	0	0	0	3	3	33
	0.00%	**0.00%**	**0.00%**	**0.00%**	**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%*	*0.18%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.01%
TOTAL	64	41	1,703	55	22,038	2,954	28,813	55,668	251,653
	0.11%	**0.07%**	**3.06%**	**0.10%**	**39.59%**	**5.31%**	**51.76%**	**100.00%**	**18.63%**
	0.11%	*0.07%*	*3.06%*	*1.86%*	*39.59%*	*5.31%*	*51.76%*	*100.00%*	*18.63%*
	0.00%	0.00%	0.00%	0.00%	0.00%	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: **590**

	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	7,919	42,026	19,460	8,864	175,124	8,100	261,493	78,269
	1.73%	**9.16%**	**4.24%**	**1.93%**	**38.18%**	**1.77%**	**57.01%**	**17.07%**
	3.03%	*16.07%*	*7.44%*	*3.39%*	*66.97%*	*3.10%*	*100.00%*	*29.93%*
	0.00%	46.07%	59.08%	55.81%	61.57%	42.39%	57.01%	50.46%
Male	7,142	49,155	13,480	6,025	106,927	3,832	186,561	75,802
	1.56%	**10.72%**	**2.94%**	**1.31%**	**23.31%**	**0.84%**	**40.68%**	**16.53%**
	3.83%	*26.35%*	*7.23%*	*3.23%*	*57.31%*	*2.05%*	*100.00%*	*40.63%*
	0.00%	53.89%	40.92%	37.93%	37.59%	20.05%	40.68%	48.87%
Unknown	0	40	1	994	2,380	7,178	10,593	1035
	0.000%	**0.01%**	**0.00%**	**0.22%**	**0.52%**	**1.57%**	**2.31%**	**0.23%**
	0.00%	*0.38%*	*0.01%*	*9.38%*	*22.47%*	*67.76%*	*100.00%*	*9.77%*
	0.00%	0.04%	0.00%	6.26%	0.84%	37.56%	2.31%	0.67%
Total	15,061	91,221	32,941	15,883	284,431	19,110	458,647	155,106
	3.28%	**19.89%**	**7.18%**	**3.46%**	**62.02%**	**4.17%**	**100.00%**	**33.82%**
	3.28%	*19.89%*	*7.18%*	*3.46%*	*62.02%*	*4.17%*	*100.00%*	*33.82%*
	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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:
More females (1,002,855 or 55.4%) than males (778,113 or 43%) are enrolled in aggregate Intramural research protocols.
More minority females (267,477 or 65.76%) than minority males (138,214 or 33.4%) are enrolled in aggregate Intramural research protocols.

Approximately 22.5% (406.759) of participants in aggregate Intramural research (1809,484) are classified as U.S. minorities.

Race: White doesn’t rank as a top racial category.
Largest identified racial minority group is Asians at 8.6% following the 1997 OMB standards.
Largest identified racial minority group is Asian/ Pacific Islander at 19.9% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.07%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/ Alaska Native at 3.2%.

Ethnicity:
4.12% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:

Largest identified racial group is Unknown at 51.76% (2nd hightest category is White at 39.6%)
Smallest identified racial group is Asian at 0.07%.
Of the 55,668 participants, 77.9% are women and 22% are men.

3.46% of participants identified 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 FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**676,551**	**131,308**		**19.41%**
%	**46.54%**	**48.91%**		
Males	**748,722**	**136,094**		**18.18%**
%	**51.50%**	**50.69%**		
Unknown	**28,516**	**1,068**		**3.75%**
%	**1.96%**	**0.40%**		
TOTAL	**1,453,789**	**268,470**	**18.47%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	1,297

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

Number of Protocols with Enrollment Data: 764

	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	2,125	18,314	29,291	406	364,099	2,219	21,327	437,781	406,576	10,204	21,001	437,781
	0.21%	**1.80%**	**2.87%**	**0.04%**	**35.72%**	**0.22%**	**2.09%**	**42.95%**	**39.89%**	**1.00%**	**2.06%**	**42.95%**
	0.49%	*4.18%*	*6.69%*	*0.09%*	*83.17%*	*0.51%*	*4.87%*	*100.00%*	*92.87%*	*2.33%*	*4.80%*	*100.00%*
	52.56%	46.94%	53.12%	44.47%	42.56%	52.58%	35.34%	42.95%	43.26%	45.53%	36.89%	42.95%
Male	1,896	20,699	25,843	507	489,647	2,001	22,948	563,541	532,854	12,207	18,480	563,541
	0.19%	**2.03%**	**2.54%**	**0.05%**	**48.04%**	**0.20%**	2.25%	**55.29%**	**52.28%**	**1.20%**	**1.81%**	**55.29%**
	0.34%	*3.67%*	*4.59%*	*0.09%*	*86.89%*	*0.36%*	4.07%	*100.00%*	*94.55%*	*2.17%*	*3.28%*	*100.00%*
	46.90%	53.06%	46.87%	55.53%	57.23%	47.42%	38.03%	55.29%	56.69%	54.46%	32.46%	55.29%
Unknown	22	1	7	0	1,819	0	16,074	17,923	475	3	17,445	17,923
	0.00%	**0.00%**	**0.00%**	0.00%	**0.18%**	**0.00%**	***1.58%***	**1.76%**	**0.05%**	**0.00%**	**1.71%**	**1.76%**
	0.12%	*0.01%*	*0.04%*	0.00%	*10.15%*	*0.00%*	*89.68%*	*100.00%*	*2.65%*	*0.02%*	*97.33%*	*100.00%*
	0.54%	0.00%	0.01%	0.00%	0.21%	0.00%	26.64%	1.76%	0.05%	0.01%	30.65%	1.76%
Total	4,043	39,014	55,141	913	855,565	4,220	60,349	1,019,245	939,905	22,414	56,926	1,019,245
	0.40%	**3.83%**	**5.41%**	**0.09%**	**83.94%**	**0.41%**	**5.92%**	**100.00%**	**92.22%**	**2.20%**	**5.59%**	**100.00%**
	0.40%	*3.83%*	*5.41%*	*0.09%*	*83.94%*	*0.41%*	*5.92%*	*100.00%*	*92.22%*	*2.20%*	*5.59%*	*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	15	4	867	11	1828	1,583	5,896	10,204	60,079
	0.07%	**0.02%**	**3.87%**	**0.38%**	**8.16%**	**7.06%**	**26.30%**	**45.53%**	**5.89%**
	0.15%	*0.04%*	*8.50%*	*0.69%*	*17.91%*	*15.51%*	*57.78%*	*100.00%*	*13.72%*
	35.71%	26.67%	52.42%	33.33%	42.81%	54.27%	43.73%	45.53%	49.62%
Male	27	11	787	22	2442	1,334	7,584	12,207	60,972
	0.12%	**0.05%**	**3.51%**	**0.75%**	**10.89%**	**5.95%**	**33.84%**	**54.46%**	**5.98%**
	0.22%	*0.09%*	*6.45%*	*1.65%*	*20.00%*	*10.93%*	*62.13%*	*100.00%*	*10.82%*
	64.29%	73.33%	47.58%	66.67%	57.19%	45.73%	56.25%	54.46%	50.36%
Unknown	0	0	0	0	0	0	3	3	33
	0.00%	**0.00%**	**0.00%**	**0.00%**	**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%*	*0.18%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.03%
TOTAL	42	15	1,654	33	4,270	2,917	13,483	22,414	121,084
	0.19%	**0.07%**	**7.38%**	**0.15%**	**19.05%**	**13.01%**	**60.15%**	**100.00%**	**11.88%**
	0.19%	*0.07%*	*7.38%*	*1.13%*	*19.05%*	*13.01%*	*60.15%*	*100.00%*	*11.88%*
	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: **533**

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	7,913	40,553	16,129	6,634	163,845	3,696	238,770	71,229
	1.82%	**9.33%**	**3.71%**	**1.53%**	**37.71%**	**0.85%**	**54.95%**	**16.39%**
	3.31%	*16.98%*	*6.76%*	*2.78%*	*68.62%*	*1.55%*	*100.00%*	*29.83%*
	52.56%	45.19%	55.72%	48.63%	60.14%	25.14%	54.95%	48.33%
Male	7,141	49,151	12,815	6,015	106,229	3,830	185,181	75,122
	1.64%	**11.31%**	**2.95%**	**1.38%**	**24.45%**	**0.88%**	**42.62%**	**17.29%**
	3.86%	*26.54%*	*6.92%*	*3.25%*	*57.36%*	*2.07%*	*100.00%*	*40.57%*
	47.44%	54.77%	44.27%	44.09%	38.99%	26.05%	42.62%	50.97%
Unknown	0	40	1	994	2,380	7,178	10,593	1035
	0.000%	**0.01%**	**0.00%**	**0.23%**	**0.55%**	**1.65%**	**2.44%**	**0.24%**
	0.00%	*0.38%*	*0.01%*	*9.38%*	*22.47%*	*67.76%*	*100.00%*	*9.77%*
	0.00%	0.04%	0.00%	7.29%	0.87%	48.82%	2.44%	0.70%
Total	15,054	89,744	28,945	13,643	272,454	14,704	434,544	147,386
	3.46%	**20.65%**	**6.66%**	**3.14%**	**62.70%**	**3.38%**	**100.00%**	**33.92%**
	3.46%	*20.65%*	*6.66%*	*3.14%*	*62.70%*	*3.38%*	*100.00%*	*33.92%*
	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: Reference Table 2A

Sex/Gender:
There were 1,523 Intramural protocols of which 130 (8.54%) were *female-only* protocols and 96 (6.3%) were *male-only* protocols.
Excluding sex-specific studies, the number of males (748,722 or 51.5%) exceeds the number of females (676,551 or 46.54%) enrolled in Intramural research protocols.
Excluding sex-specific studies, the number of minority males (136,094 or 50.7%) exceeds the number of females (131,308 or 48.9%) enrolled in Intramural research protocols.

Approximately 18.5% (268,470) of participants in aggregate Intramural research excluding sex-specific studies (1,453,789) are classified as U.S. minorities.

Race:
Largest identified racial group is White at 83.94% following the 1997 OMB standards and 62.7% following the 1977 OMB standards.
Largest identified racial minority group is Black at 5.4% following the 1997 OMB standards.
Largest identified racial minority group is Asian/Pacific Islander at 20.65% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.4%.
According to the 1977 OMB standards, the smallest identified racial minority group is Hispanic at 3.14%.

Ethnicity:
2.22% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is Unknown at 60.15 % (2nd hightest category is White at 19%)
Smallest identified racial group is Asian at 0.07%
Of the 22,414 participants, 45.53% are women and 54.46% are men.
3.13% of participants identified as Hispanic according to the 1977 OMB standards.

Table 9A. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	16,988	9,609		56.56%
%	53.97%	56.51%		
Males	14,488	7,395		51.04%
%	46.03%	43.49%		
Unknown	0	0		0.00%
%	0.00%	0.00%		
TOTAL	31,476	17,004	54.02%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	44

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

Number of Protocols with Enrollment Data: 27

	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	89	493	1	5,179	265	3,725	9,760	5,769	2,526	1,466	9,761
	0.05%	0.56%	3.11%	0.01%	32.71%	1.67%	23.53%	61.65%	36.44%	15.96%	9.26%	61.65%
	0.08%	0.91%	5.05%	0.01%	53.06%	2.72%	38.17%	100.00%	59.10%	25.88%	15.02%	100.00%
	40.00%	45.41%	64.70%	100.00%	57.03%	55.44%	70.38%	61.65%	57.36%	91.89%	48.45%	61.65%
Male	12	107	269	0	3,902	213	1,568	6,071	4,288	223	1,560	6,071
	0.08%	0.68%	1.70%	0.00%	24.65%	1.35%	9.90%	38.35%	27.08%	1.41%	9.85%	38.35%
	0.20%	1.76%	4.43%	0.00%	64.27%	3.51%	25.83%	100.00%	70.63%	3.67%	25.70%	100.00%
	60.00%	54.59%	35.30%	0.00%	42.97%	44.56%	29.62%	38.35%	42.64%	8.11%	51.55%	38.35%
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	20	196	762	1	9,081	478	5,293	15,831	10,057	2,749	3,026	15,832
	0.13%	1.24%	4.81%	0.01%	57.36%	3.02%	33.43%	100.00%	63.52%	17.36%	19.11%	100.00%
	0.13%	1.24%	4.81%	0.01%	57.36%	3.02%	33.43%	100.00%	63.52%	17.36%	19.11%	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	2,526	2,526	3,382
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	91.89%	91.89%	21.36%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	34.65%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	91.89%	91.89%	80.41%
Male	0	0	0	0	0	0	223	223	824
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	8.11%	8.11%	5.20%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	13.57%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	8.11%	8.11%	19.59%
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	0	0	0	0	0	0	2,749	2,749	4,206
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	26.57%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	26.57%
	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: **17**

	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	126	5,993	77	31	996	5	7,228	6,227
	0.81%	**38.31%**	**0.49%**	**0.20%**	**6.37%**	**0.03%**	**46.20%**	**39.80%**
	1.74%	*82.91%*	*1.07%*	*0.43%*	*13.78%*	*0.07%*	*100.00%*	*86.15%*
	0.00%	48.67%	33.92%	38.27%	35.19%	29.41%	46.20%	48.66%
Male	50	6,321	150	50	1,834	12	8,417	6,571
	0.32%	**40.40%**	**0.96%**	**0.32%**	**11.72%**	**0.08%**	**53.80%**	**42.00%**
	0.59%	*75.10%*	*1.78%*	*0.59%*	*21.79%*	*0.14%*	*100.00%*	*78.07%*
	0.00%	51.33%	66.08%	61.73%	64.81%	70.59%	53.80%	51.34%
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	176	12,314	227	81	2,830	17	15,645	12,798
	1.12%	**78.71%**	**1.45%**	**0.52%**	**18.09%**	**0.11%**	**100.00%**	**81.80%**
	1.12%	*78.71%*	*1.45%*	*0.52%*	*18.09%*	*0.11%*	*100.00%*	*81.80%*
	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 females (16,988 or 53.97%) than males (14,488 or 46%) are enrolled in aggregate Intramural research protocols.
More minority females (9,609 or 56.5%) than minority males (7,395 or 43.5%) are enrolled in aggregate Intramural research protocols.

Approximately 54% (17,004) of participants in aggregate Intramural research (31,476) are classified as U.S. minorities.

Race: White doesn’t rank as a top racial category.
Largest identified racial minority group is Black or African American at 4.8% following the 1997 OMB standards.
Largest identified racial minority group is Asian/ Pacific Islander at 78.7% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.01%.
According to the 1977 OMB standards, the smallest identified racial minority group is Hispanic at 0.5%.

Ethnicity:
17.36% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is Unknown/Other at 100%
Of the 2,749 participants, 91.9% are women and 8.1% are men.
0.52% of participants identified 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 FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	14,745	7,368		49.97%
%	50.75%	49.99%		
Males	14,310	7,370		51.50%
%	49.25%	50.01%		
Unknown	0	0		0.00%
%	0.00%	0.00%		
TOTAL	29,055	14,738	50.72%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 37

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

Number of Protocols with Enrollment Data: 22

	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	89	492	1	5,176	265	1,486	7,517	5,765	286	1,466	7,517
	0.06%	**0.66%**	**3.62%**	**0.01%**	**38.10%**	**1.95%**	**10.94%**	**55.33%**	**42.44%**	**2.11%**	**10.79%**	**55.33%**
	0.11%	*1.18%*	*6.55%*	*0.01%*	*68.86%*	*3.53%*	*19.77%*	*100.00%*	*76.69%*	*3.80%*	*19.50%*	*100.00%*
	40.00%	45.41%	64.65%	100.00%	57.04%	55.44%	48.66%	55.33%	57.36%	56.19%	48.45%	55.33%
Male	12	107	269	0	3,899	213	1,568	6,068	4,285	223	1,560	6,068
	0.09%	**0.79%**	**1.98%**	**0.00%**	**28.70%**	**1.57%**	11.54%	**44.67%**	**31.54%**	**1.64%**	**11.48%**	**44.67%**
	0.20%	*1.76%*	*4.43%*	*0.00%*	*64.26%*	*3.51%*	25.84%	*100.00%*	*70.62%*	*3.68%*	*25.71%*	*100.00%*
	60.00%	54.59%	35.35%	0.00%	42.96%	44.56%	51.34%	44.67%	42.64%	43.81%	51.55%	44.67%
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	20	196	761	1	9,075	478	3,054	13,585	10,050	509	3,026	13,585
	0.15%	**1.44%**	**5.60%**	**0.01%**	**66.80%**	**3.52%**	**22.48%**	**100.00%**	**73.98%**	**3.75%**	**22.27%**	**100.00%**
	0.15%	*1.44%*	*5.60%*	*0.01%*	66.80%	*3.52%*	*22.48%*	*100.00%*	*73.98%*	*3.75%*	*22.27%*	*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	286	286	1,141
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**56.19%**	**56.19%**	**8.40%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*15.18%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.19%	56.19%	58.07%
Male	0	0	0	0	0	0	223	223	824
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**43.81%**	**43.81%**	**6.07%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*13.58%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.81%	43.81%	41.93%
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	0	0	0	0	0	0	509	509	1,965
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**100.00%**	**14.46%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*14.46%*
	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 10A.

Number of Protocols with Enrollment Data: **15**

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	126	5,993	77	31	996	5	7,228	6,227
	0.81%	**38.74%**	**0.50%**	**0.20%**	**6.44%**	**0.03%**	**46.72%**	**40.25%**
	1.74%	*82.91%*	*1.07%*	*0.43%*	*13.78%*	*0.07%*	*100.00%*	*86.15%*
	72.00%	48.68%	37.02%	39.24%	37.15%	31.25%	46.72%	48.75%
Male	49	6,318	131	48	1,685	11	8,242	6,546
	0.32%	**40.84%**	**0.85%**	**0.31%**	**10.89%**	**0.07%**	**53.28%**	**42.31%**
	0.59%	*76.66%*	*1.59%*	*0.58%*	*20.44%*	*0.13%*	*100.00%*	*79.42%*
	28.00%	51.32%	62.98%	60.76%	62.85%	68.75%	53.28%	51.25%
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	175	12,311	208	79	2,681	16	15,470	12,773
	1.13%	**79.58%**	**1.34%**	**0.51%**	**17.33%**	**0.10%**	**100.00%**	**82.57%**
	1.13%	*79.58%*	*1.34%*	*0.51%*	*17.33%*	*0.10%*	*100.00%*	*82.57%*
	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: Reference Table 4A

Sex/Gender:

There were 44 PhaseIII Intramural protocols of which 3 (6.8%) were *female-only* protocols and 4 (9.1%) were *male-only* protocols.
Excluding sex-specific studies, the number of females (14,745 or 50.75%) exceeds the number of males (14,310 or 49.25%) enrolled in PhaseIII Intramural research protocols.
Excluding sex-specific studies, the number of minority males (7,370 or 50.01%) exceeds the number of females (7,368 or 49.99%) enrolled in Phase III Intramural research protocols.

Approximately 50.72% (14,7389) of participants in aggregate PhaseIII Intramural research excluding sex-specific studies (29,055) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 66.8 % following the 1997 OMB standards .
Largest identified racial minority group is Asian/ Pacific Islander at 79.58% following the 1977 OMB standards.
Largest identified racial minority group is Black or African American at 5.6% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is Hispanic at 0.51%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.01%.

Ethnicity:

3.75% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is Unknown at 100%
Of the 509 participants, 56.2% are women and 43.8% are men.
0.5% of participants identified as Hispanic according to the 1977 OMB standards.

Table 11A. DOMESTIC Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**7,684,453**	**2,200,474**		**28.64%**
%	**67.26%**	**66.66%**		
Males	**3,566,577**	**1,075,138**		**30.14%**
%	**31.22%**	**32.57%**		
Unknown	**174,671**	**25,523**		**14.61%**
%	**1.53%**	**0.77%**		
TOTAL	**11,425,701**	**3,301,135**	**28.89%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	10,294

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

Number of Protocols with Enrollment Data: **8,933**

	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	78,746	622,637	710,350	21,249	4,690,433	106,926	679,820	6,910,161	5,763,444	534,174	612,543	6,910,161
	0.77%	**6.10%**	**6.96%**	**0.21%**	**45.97%**	**1.05%**	**6.66%**	**67.72%**	**56.48%**	**5.24%**	**6.00%**	**67.72%**
	1.14%	*9.01%*	*10.28%*	*0.31%*	*67.88%*	*1.55%*	*9.84%*	*100.00%*	*83.41%*	*7.73%*	*8.86%*	*100.00%*
	70.91%	65.78%	68.82%	60.47%	68.52%	59.98%	64.41%	67.72%	68.74%	67.06%	59.89%	67.72%
Male	31,668	320,088	313,187	13,828	2,111,033	67,559	278,483	3,135,846	2,561,151	254,802	319,893	3,135,846
	0.31%	**3.14%**	**3.07%**	**0.14%**	**20.69%**	**0.66%**	2.73%	**30.73%**	**25.10%**	**2.50%**	**3.14%**	**30.73%**
	1.01%	*10.21%*	*9.99%*	*0.44%*	*67.32%*	*2.15%*	8.88%	*100.00%*	*81.67%*	*8.13%*	*10.20%*	*100.00%*
	28.52%	33.81%	30.34%	39.35%	30.84%	37.90%	26.39%	30.73%	30.55%	31.99%	31.28%	30.73%
Unknown	634	3,888	8,662	65	43,494	3,790	97,133	157,666	59,765	7,580	90,321	157,666
	0.01%	**0.04%**	**0.08%**	0.00%	**0.43%**	**0.04%**	**0.95%**	**1.55%**	**0.59%**	**0.07%**	**0.89%**	**1.55%**
	0.40%	*2.47%*	*5.49%*	0.04%	*27.59%*	*2.40%*	*61.61%*	*100.00%*	*37.91%*	*4.81%*	*57.29%*	*100.00%*
	0.57%	0.41%	0.84%	0.18%	0.64%	2.13%	9.20%	1.55%	0.71%	0.95%	8.83%	1.55%
Total	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
	1.09%	**9.28%**	**10.12%**	**0.34%**	**67.08%**	**1.75%**	**10.34%**	**100.00%**	**82.17%**	**7.81%**	**10.02%**	**100.00%**
	1.09%	*9.28%*	*10.12%*	*0.34%*	*67.08%*	*1.75%*	*10.34%*	*100.00%*	*82.17%*	*7.81%*	*10.02%*	*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	8,011	4,415	11,785	968	275,061	27,943	205,991	534,174	2,020,960
	1.01%	**0.55%**	**1.48%**	**1.97%**	**34.53%**	**3.51%**	**25.86%**	**67.06%**	**19.81%**
	1.50%	*0.83%*	*2.21%*	*3.46%*	*51.49%*	*5.23%*	*38.56%*	*100.00%*	*29.25%*
	0.00%	0.00%	0.00%	0.00%	0.00%	56.85%	62.58%	67.06%	67.20%
Male	7,472	2,117	8,042	526	99169	20,619	116,857	254,802	962,356
	0.94%	**0.27%**	**1.01%**	**1.07%**	**12.45%**	**2.59%**	**14.67%**	**31.99%**	**9.43%**
	2.93%	*0.83%*	*3.16%*	*2.55%*	*38.92%*	*8.09%*	*45.86%*	*100.00%*	*30.69%*
	0.00%	0.00%	0.00%	0.00%	0.00%	41.95%	35.50%	31.99%	32.00%
Unknown	15	8	43	11	600	588	6,315	7,580	23,954
	0.00%	**0.00%**	**0.01%**	**0.02%**	**0.08%**	**0.07%**	**0.79%**	**0.95%**	**0.23%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*15.19%*
	0.00%	0.00%	0.00%	0.00%	0.00%	1.20%	1.92%	0.95%	0.80%
TOTAL	15,498	6,540	19,870	1,505	374,830	49,150	329,163	796,556	3,007,270
	1.95%	**0.82%**	**2.49%**	**3.06%**	**47.06%**	**6.17%**	**41.32%**	**100.00%**	**29.47%**
	1.95%	*0.82%*	*2.49%*	*3.06%*	*47.06%*	*6.17%*	*41.32%*	*100.00%*	*29.47%*
	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%	100.00%

Table 11 A

Number of Protocols with Enrollment Data: **1,361**

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	10,542	31,260	92,934	44,778	565,910	28,868	774,292	179,514
	0.86%	**2.56%**	**7.60%**	**3.66%**	**46.31%**	**2.36%**	**63.36%**	**14.69%**
	1.36%	*4.04%*	*12.00%*	*5.78%*	*73.09%*	*3.73%*	*100.00%*	*23.18%*
	0.00%	60.46%	62.70%	60.26%	65.30%	46.96%	63.36%	61.09%
Male	9,009	20,205	54,657	28,911	298,197	19,752	430,731	112,782
	0.74%	**1.65%**	**4.47%**	**2.37%**	**24.40%**	**1.62%**	**35.25%**	**9.23%**
	2.09%	*4.69%*	*12.69%*	*6.71%*	*69.23%*	*4.59%*	*100.00%*	*26.18%*
	0.00%	39.08%	36.87%	38.90%	34.41%	32.13%	35.25%	38.38%
Unknown	77	236	633	623	2,576	12,860	17,005	1569
	0.006%	**0.02%**	**0.05%**	**0.05%**	**0.21%**	**1.05%**	**1.39%**	**0.13%**
	0.45%	*1.39%*	*3.72%*	*3.66%*	*15.15%*	*75.62%*	*100.00%*	*9.23%*
	0.00%	0.46%	0.43%	0.84%	0.30%	20.92%	1.39%	0.53%
Total	19,628	51,701	148,224	74,312	866,683	61,480	1,222,028	293,865
	1.61%	**4.23%**	**12.13%**	**6.08%**	**70.92%**	**5.03%**	**100.00%**	**24.05%**
	1.61%	*4.23%*	*12.13%*	*6.08%*	*70.92%*	*5.03%*	*100.00%*	*24.05%*
	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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:
More females (7,864,453 or 67.26%) than males (3,566,577 or 31.22%) are enrolled in aggregate Domestic extramural and intramural research protocols.

More minority females (2,200,474 or 66.66%) than minority males (1,075,138 or 32.57 %) are enrolled in aggregate Domestic extramural and intramural research protocols.

Approximately 28.89% (3,301,135) of participants in aggregate Domestic extramural and intramural research (11,425,701) are classified as U.S. minorities.

Race: White doesn't rank as a top racial category.
Largest identified racial minority group is Unknown at 10.34% and Black or African American at 10.12 % following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 12.13% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.34%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/ Alaska Native at 1.61%.

Ethnicity:
7.81% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is White at 47.06% (2nd hightest category is Unknown at 41.32%)
Smallest identified racial group is Asian at 0.82%.
Of the 796,556 participants, 67.06% are women and 31.99% are men.
6.08% of participants identified as Hispanic according to the 1977 OMB standards.

Table 12A. DOMESTIC Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**6,905,294**	**2,076,882**		**30.08%**
%	**69.25%**	**66.94%**		
Males	**2,914,327**	**1,000,359**		**34.33%**
%	**29.23%**	**32.24%**		
Unknown	**151,816**	**25,490**		**16.79%**
%	**1.52%**	**0.82%**		
TOTAL	**9,971,437**	**3,102,731**	**31.12%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	8,851

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

Number of Protocols with Enrollment Data: **8,064**

	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	75,255	615,029	672,362	20,798	4,209,239	99,445	656,904	6,349,032	5,243,492	507,943	597,597	6,349,032
	0.83%	**6.75%**	**7.38%**	**0.23%**	**46.20%**	**1.09%**	**7.21%**	**69.69%**	**57.55%**	**5.58%**	**6.56%**	**69.69%**
	1.19%	*9.69%*	*10.59%*	*0.33%*	*66.30%*	*1.57%*	*10.35%*	*100.00%*	*82.59%*	*8.00%*	*9.41%*	*100.00%*
	71.24%	66.09%	69.33%	60.85%	71.33%	58.44%	65.76%	69.69%	71.17%	66.80%	60.84%	69.69%
Male	29,770	311,727	288,796	13,316	1,650,108	66,926	258,911	2,619,554	2,065,110	244,872	309,572	2,619,554
	0.33%	**3.42%**	**3.17%**	**0.15%**	**18.11%**	**0.73%**	2.84%	**28.75%**	**22.67%**	**2.69%**	**3.40%**	**28.75%**
	1.14%	*11.90%*	*11.02%*	*0.51%*	*62.99%*	*2.55%*	9.88%	*100.00%*	*78.83%*	*9.35%*	*11.82%*	*100.00%*
	28.18%	33.50%	29.78%	38.96%	27.96%	39.33%	25.92%	28.75%	28.03%	32.20%	31.52%	28.75%
Unknown	612	3,888	8,655	65	41,788	3,790	83,200	141,998	59,404	7,577	75,017	141,998
	0.01%	**0.04%**	**0.09%**	0.00%	**0.46%**	**0.04%**	***0.91%***	**1.56%**	**0.65%**	**0.08%**	**0.82%**	**1.56%**
	0.43%	*2.74%*	*6.10%*	0.05%	*29.43%*	*2.67%*	*58.59%*	*100.00%*	*41.83%*	*5.34%*	*52.83%*	*100.00%*
	0.58%	0.42%	0.89%	0.19%	0.71%	2.23%	8.33%	1.56%	0.81%	1.00%	7.64%	1.56%
Total	105,637	930,644	969,813	34,179	5,901,135	170,161	999,015	9,110,584	7,368,006	760,392	982,186	9,110,584
	1.16%	**10.21%**	**10.64%**	**0.38%**	**64.77%**	**1.87%**	**10.97%**	**100.00%**	**80.87%**	**8.35%**	**10.78%**	**100.00%**
	1.16%	*10.21%*	*10.64%*	*0.38%*	*64.77%*	*1.87%*	*10.97%*	*100.00%*	*80.87%*	*8.35%*	*10.78%*	*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	7,976	4,385	11,555	936	255,664	27,870	199,557	507,943	1,938,110
	1.05%	**0.58%**	**1.52%**	**1.91%**	**33.62%**	**3.67%**	**26.24%**	**66.80%**	**21.27%**
	1.57%	*0.86%*	*2.27%*	*3.36%*	*50.33%*	*5.49%*	*39.29%*	*100.00%*	*30.53%*
	51.67%	67.47%	59.59%	64.51%	72.40%	56.86%	63.25%	66.80%	67.32%
Male	7,445	2,106	7,793	504	96840	20,558	109,626	244,872	917,001
	0.98%	**0.28%**	**1.02%**	**1.03%**	**12.74%**	**2.70%**	**14.42%**	**32.20%**	**10.07%**
	3.04%	*0.86%*	*3.18%*	*2.45%*	*39.55%*	*8.40%*	*44.77%*	*100.00%*	*35.01%*
	48.23%	32.40%	40.19%	34.73%	27.43%	41.94%	34.75%	32.20%	31.85%
Unknown	15	8	43	11	600	588	6312	7,577	23,922
	0.00%	**0.00%**	**0.01%**	**0.02%**	**0.08%**	**0.08%**	**0.83%**	**1.00%**	**0.26%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*16.85%*
	0.10%	0.12%	0.22%	0.76%	0.17%	1.20%	2.00%	1.00%	0.83%
TOTAL	15,436	6,499	19,391	1,451	353,104	49,016	315,495	760,392	2,879,033
	2.03%	**0.85%**	**2.55%**	**0.19%**	**46.44%**	**6.45%**	**41.49%**	**100.00%**	**31.60%**
	2.03%	*0.85%*	*2.55%*	*2.96%*	*46.44%*	*6.45%*	*41.49%*	*100.00%*	*31.60%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 12A

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

Number of Protocols with Enrollment Data: **787**

	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	2,626	24,727	73,822	37,597	396,237	21,253	556,262	138,772
	0.31%	**2.87%**	**8.58%**	**4.37%**	**46.03%**	**2.47%**	**64.62%**	**16.12%**
	0.47%	*4.45%*	*13.27%*	*6.76%*	*71.23%*	*3.82%*	*100.00%*	*24.95%*
	57.46%	61.04%	63.67%	59.99%	66.73%	49.03%	64.62%	62.04%
Male	1,867	15,545	41,492	24,454	195,007	16,408	294,773	83,358
	0.22%	**1.81%**	**4.82%**	**2.84%**	**22.65%**	**1.91%**	**34.24%**	**9.68%**
	0.63%	*5.27%*	*14.08%*	*8.30%*	*66.15%*	*5.57%*	*100.00%*	*28.28%*
	40.85%	38.38%	35.79%	39.02%	32.84%	37.86%	34.24%	37.26%
Unknown	77	236	632	623	2,568	5,682	9,818	1,568
	0.009%	**0.03%**	**0.07%**	**0.07%**	**0.30%**	**0.66%**	**1.14%**	**0.18%**
	0.78%	*2.40%*	*6.44%*	*6.35%*	*26.16%*	*57.87%*	*100.00%*	*15.97%*
	1.68%	0.58%	0.55%	0.99%	0.43%	13.11%	1.14%	0.70%
Total	4,570	40,508	115,946	62,674	593,812	43,343	860,853	223,698
	0.53%	**4.71%**	**13.47%**	**7.28%**	**68.98%**	**5.03%**	**100.00%**	**25.99%**
	0.53%	*4.71%*	*13.47%*	*7.28%*	*68.98%*	*5.03%*	*100.00%*	*25.99%*
	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 females (6,905,204 or 69.2%) than males (2,914,327 or 29.2%) are enrolled in aggregate Domestic extramural research protocols.
More minority females (2,076,882 or 66.9%) than minority males (1,000,359 or 32.24 %) are enrolled in aggregate Domestic extramural research protocols.

Approximately 31.12% (3,102,731) of participants in aggregate Domestic extramural research (9,971,437) are classified as U.S. minorities.

Race: White doesn't rank as a top racial category.
Largest identified racial minority group is Black or African American at 10.64 % following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 13.5% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.4%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/ Alaska Native at 0.53%.

Ethnicity:
8.35% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:

Largest identified racial group is White at 46.44% (2nd hightest category is Unknown at 41.5%)
Smallest identified racial group is Hawaiian/Pacific Islander at 0.19%.
Of the 760,392 participants, 64.62% are women and 34.24% are men.

7.28% of participants identified as Hispanic according to the 1977 OMB standards.

Table 13A. DOMESTIC Aggregate Enrollment Data for Intramural Research Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**779,159**	**123,592**		**15.86%**
%	**53.58%**	**62.29%**		
Males	**652,250**	**74,779**		**11.46%**
%	**44.85%**	**37.69%**		
Unknown	**22,855**	**33**		**0.14%**
%	**1.57%**	**0.02%**		
TOTAL	**1,454,264**	**198,404**	**13.64%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 1,443

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

Number of Protocols with Enrollment Data: **869**

	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	3,491	7,608	37,988	451	481,194	7,481	22,916	561,129	519,952	26,231	14,946	561,129
	0.32%	**0.70%**	**3.48%**	**0.04%**	**44.02%**	**0.68%**	**2.10%**	**51.33%**	**47.57%**	**2.40%**	**1.37%**	**51.33%**
	0.62%	*1.36%*	*6.77%*	*0.08%*	*85.75%*	*1.33%*	*4.08%*	*100.00%*	*92.66%*	*4.67%*	*2.66%*	*100.00%*
	64.52%	47.64%	60.89%	46.83%	50.98%	92.20%	40.62%	51.33%	51.16%	72.53%	36.84%	51.33%
Male	1,898	8,361	24,391	512	460,925	633	19,572	516,292	496,041	9,930	10,321	516,292
	0.17%	**0.76%**	**2.23%**	**0.05%**	**42.17%**	**0.06%**	1.79%	**47.23%**	**45.38%**	**0.91%**	**0.94%**	**47.23%**
	0.37%	*1.62%*	*4.72%*	*0.10%*	*89.28%*	*0.12%*	3.79%	*100.00%*	*96.08%*	*1.92%*	*2.00%*	*100.00%*
	35.08%	52.36%	39.10%	53.17%	48.84%	7.80%	34.69%	47.23%	48.81%	27.46%	25.44%	47.23%
Unknown	22	0	7	0	1706	0	13,933	15,668	361	3	15,304	15,668
	0.00%	**0.00%**	**0.00%**	0.00%	**0.16%**	**0.00%**	*1.27%*	**1.43%**	**0.03%**	**0.00%**	**1.40%**	**1.43%**
	0.14%	*0.00%*	*0.04%*	0.00%	*10.89%*	*0.00%*	*88.93%*	*100.00%*	*2.30%*	*0.02%*	*97.68%*	*100.00%*
	0.41%	0.00%	0.01%	0.00%	0.18%	0.00%	24.69%	1.43%	0.04%	0.01%	37.72%	1.43%
Total	5,411	15,969	62,386	963	943,825	8,114	56,421	1,093,089	1,016,354	36,164	40,571	1,093,089
	0.50%	**1.46%**	**5.71%**	**0.09%**	**86.34%**	**0.74%**	**5.16%**	**100.00%**	**92.98%**	**3.31%**	**3.71%**	**100.00%**
	0.50%	*1.46%*	*5.71%*	*0.09%*	*86.34%*	*0.74%*	*5.16%*	*100.00%*	*92.98%*	*3.31%*	*3.71%*	*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	35	30	230	32	19,397	73	6,434	26,231	82,850
	0.10%	**0.08%**	**0.64%**	**23.88%**	**53.64%**	**0.20%**	**17.79%**	**72.53%**	**7.58%**
	0.13%	*0.11%*	*0.88%*	*43.84%*	*73.95%*	*0.28%*	*24.53%*	*100.00%*	*14.76%*
	56.45%	73.17%	48.02%	59.26%	89.28%	54.48%	47.07%	72.53%	64.61%
Male	27	11	249	22	2,329	61	7,231	9,930	45,355
	0.07%	**0.03%**	**0.69%**	**16.42%**	**6.44%**	**0.17%**	**20.00%**	**27.46%**	**4.15%**
	0.27%	*0.11%*	*2.51%*	*36.07%*	*23.45%*	*0.61%*	*72.82%*	*100.00%*	*8.78%*
	43.55%	26.83%	51.98%	40.74%	10.72%	45.52%	52.90%	27.46%	35.37%
Unknown	0	0	0	0	0	0	3	3	32
	0.00%	**0.00%**	**0.00%**	**0.00%**	**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%*	*0.20%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.02%
TOTAL	62	41	479	54	21,726	134	13,668	36,164	128,237
	0.17%	**0.11%**	**1.32%**	**0.15%**	**60.08%**	**0.37%**	**37.79%**	**100.00%**	**11.73%**
	0.17%	*0.11%*	*1.32%*	*40.30%*	*60.08%*	*0.37%*	*37.79%*	*100.00%*	*11.73%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 13A

Number of Protocols with Enrollment Data: **574**

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	7,916	6,533	19,112	7,181	169,673	7,615	218,030	40,742
	2.19%	**1.81%**	**5.29%**	**1.99%**	**46.98%**	**2.11%**	**60.37%**	**11.28%**
	3.63%	*3.00%*	*8.77%*	*3.29%*	*77.82%*	*3.49%*	*100.00%*	*18.69%*
	52.57%	58.37%	59.21%	61.70%	62.18%	41.99%	60.37%	58.06%
Male	7,142	4,660	13,165	4,457	103,190	3,344	135,958	29,424
	1.98%	**1.29%**	**3.65%**	**1.23%**	**28.57%**	**0.93%**	**37.64%**	**8.15%**
	5.25%	*3.43%*	*9.68%*	*3.28%*	*75.90%*	*2.46%*	*100.00%*	*21.64%*
	47.43%	41.63%	40.79%	38.30%	37.82%	18.44%	37.64%	41.93%
Unknown	0	0	1	0	8	7,178	7,187	1
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**1.99%**	**1.99%**	**0.00%**
	0.00%	*0.00%*	*0.01%*	*0.00%*	*0.11%*	*99.87%*	*100.00%*	*0.01%*
	0.00%	0.00%	0.00%	0.00%	0.00%	39.58%	1.99%	0.00%
Total	15,058	11,193	32,278	11,638	272,871	18,137	361,175	70,167
	4.17%	**3.10%**	**8.94%**	**3.22%**	**75.55%**	**5.02%**	**100.00%**	**19.43%**
	4.17%	*3.10%*	*8.94%*	*3.22%*	*75.55%*	*5.02%*	*100.00%*	*19.43%*
	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 females (779,159 or 53.6%) than males (652,250 or 44.85%) are enrolled in aggregate Domestic Intramural research protocols.
More minority females (123,592 or 62.3%) than minority males (74,779 or 37.7%) are enrolled in aggregate Domestic Intramural research protocols.

Approximately 13.6% (198,404) of participants in aggregate Domestic Intramural research (1,454,264) are classified as U.S. minorities.

Race: White doesn’t rank as a top racial category.
Largest identified racial minority group is Black or African American at 5.7% following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 8.94% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.09%.
According to the 1977 OMB standards, the smallest identified racial minority group is Asian/ Pacific Islander at 3.1%.

Ethnicity:
3.31% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is White at 60% (2nd hightest category is Unknown at 37.8%)
Smallest identified racial group is Asian at 0.11%.
Of the 36,164 participants, 72.5% are women and 27.5% are men.
3.2% of participants identified as Hispanic according to the 1977 OMB standards.

Table 14A. DOMESTIC Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	251,055	51,855		20.65%
%	65.02%	64.32%		
Males	130,852	28,473		21.76%
%	33.89%	35.32%		
Unknown	4,209	294		6.99%
%	1.09%	0.36%		
TOTAL	386,116	80,622	20.88%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	524

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

Number of Protocols with Enrollment Data: 333

	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	1,742	2,223	13,021	261	51,745	1,999	16,115	87,106	64,148	6,921	16,037	87,106
	0.98%	1.25%	7.34%	0.15%	29.18%	1.13%	9.09%	49.13%	36.18%	3.90%	9.04%	49.13%
	2.00%	2.55%	14.95%	0.30%	59.40%	2.29%	18.50%	100.00%	73.64%	7.95%	18.41%	100.00%
	64.42%	43.45%	57.59%	49.34%	47.26%	55.54%	48.46%	49.13%	48.70%	53.07%	49.29%	49.13%
Male	961	2,890	9,562	268	57,642	1,595	13,215	86,133	67,451	5,866	12,816	86,133
	0.54%	1.63%	5.39%	0.15%	32.51%	0.90%	7.45%	48.58%	38.04%	3.31%	7.23%	48.58%
	1.12%	3.36%	11.10%	0.31%	66.92%	1.85%	15.34%	100.00%	78.31%	6.81%	14.88%	100.00%
	35.54%	56.49%	42.29%	50.66%	52.64%	44.32%	39.74%	48.58%	51.20%	44.98%	39.39%	48.58%
Unknown	1	3	25	0	109	5	3,927	4,070	135	254	3,681	4,070
	0.00%	0.00%	0.01%	0.00%	0.06%	0.00%	2.21%	2.30%	0.08%	0.14%	2.08%	2.30%
	0.02%	0.07%	0.61%	0.00%	2.68%	0.12%	96.49%	100.00%	3.32%	6.24%	90.44%	100.00%
	0.04%	0.06%	0.11%	0.00%	0.10%	0.14%	11.81%	2.30%	0.10%	1.95%	11.31%	2.30%
Total	2,704	5,116	22,608	529	109,496	3,599	33,257	177,309	131,734	13,041	32,534	177,309
	1.53%	2.89%	12.75%	0.30%	61.75%	2.03%	18.76%	100.00%	74.30%	7.35%	18.35%	100.00%
	1.53%	2.89%	12.75%	0.30%	61.75%	2.03%	18.76%	100.00%	74.30%	7.35%	18.35%	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	370	30	262	28	3122	381	2,728	6,921	25,096
	2.84%	0.23%	2.01%	3.93%	23.94%	2.92%	20.92%	53.07%	14.15%
	5.35%	0.43%	3.79%	7.35%	45.11%	5.50%	39.42%	100.00%	28.81%
	80.79%	63.83%	51.68%	70.00%	56.31%	53.51%	47.58%	53.07%	54.76%
Male	88	17	245	12	2418	330	2,756	5,866	20,450
	0.67%	0.13%	1.88%	1.69%	18.54%	2.53%	21.13%	44.98%	11.53%
	1.50%	0.29%	4.18%	3.64%	41.22%	5.63%	46.98%	100.00%	23.74%
	19.21%	36.17%	48.32%	30.00%	43.61%	46.35%	48.07%	44.98%	44.62%
Unknown	0	0	0	0	4	1	249	254	287
	0.00%	0.00%	0.00%	0.00%	0.03%	0.01%	1.91%	1.95%	0.16%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	7.05%
	0.00%	0.00%	0.00%	0.00%	0.07%	0.14%	4.34%	1.95%	0.63%
TOTAL	458	47	507	40	5,544	712	5,733	13,041	45,833
	3.51%	0.36%	3.89%	0.31%	42.51%	5.46%	43.96%	100.00%	25.85%
	3.51%	0.36%	3.89%	5.62%	42.51%	5.46%	43.96%	100.00%	25.85%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 14A

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

Number of Protocols with Enrollment Data: **191**

	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	633	3,599	15,770	6,757	133,513	3,677	163,949	26,759
	0.30%	**1.72%**	**7.55%**	**3.24%**	**63.94%**	**1.76%**	**78.52%**	**12.82%**
	0.39%	*2.20%*	*9.62%*	*4.12%*	*81.44%*	*2.24%*	*100.00%*	*16.32%*
	77.20%	81.06%	78.47%	71.65%	79.30%	65.00%	78.52%	76.92%
Male	187	839	4,323	2,674	34,824	1,872	44,719	8,023
	0.09%	**0.40%**	**2.07%**	**1.28%**	**16.68%**	**0.90%**	**21.42%**	**3.84%**
	0.42%	*1.88%*	*9.67%*	*5.98%*	*77.87%*	*4.19%*	*100.00%*	*17.94%*
	22.80%	18.90%	21.51%	28.35%	20.68%	33.09%	21.42%	23.06%
Unknown	0	2	5	0	24	108	139	7
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.05%**	**0.07%**	**0.00%**
	0.00%	*1.44%*	*3.60%*	*0.00%*	*17.27%*	*77.70%*	*100.00%*	*5.04%*
	0.00%	0.05%	0.02%	0.00%	0.01%	1.91%	0.07%	0.02%
Total	820	4,440	20,098	9,431	168,361	5,657	208,807	34,789
	0.39%	**2.13%**	**9.63%**	**4.52%**	**80.63%**	**2.71%**	**100.00%**	**16.66%**
	0.39%	*2.13%*	*9.63%*	*4.52%*	*80.63%*	*2.71%*	*100.00%*	*16.66%*
	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 females (251,055 or 65%) than males (130,852 or 33.9%) are enrolled in aggregate Phase III Domestic extramural research protocols.
More minority females (51,855 or 64.3%) than minority males (28,473 or 35.3%) are enrolled in aggregate Phase III Domestic extramural research protocols.

Approximately 20.9% (80,622) of participants in aggregate PhaseIII Domestic extramural research (386,116) are classified as U.S. minorities.

Race: White doesn’t rank as a top racial category.
Largest identified racial minority group is Black or African Americanat 12.75 % following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 9.63% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.3%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/ Alaska Native at 0.4%.

Ethnicity:
7.35% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is Unknow at 43.96% (2nd hightest category is White at 42.51%)
Smallest identified racial group is Hawaiian/Pacific Islander at 0.3%.
Of the 13,041 participants, 53% are women and 45% are men.
4.52% of participants identified as Hispanic according to the 1977 OMB standards.

Table 15A. DOMESTIC Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	7,412	1,339		18.07%
%	52.27%	55.51%		
Males	6,769	1,073		15.85%
%	47.73%	44.49%		
Unknown	0	0		0.00%
%	0.00%	0.00%		
TOTAL	14,181	2,412	17.01%	
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: 24

	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	89	433	1	5,179	265	179	6,154	5,709	286	159	6,154
	0.07%	0.83%	4.01%	0.01%	48.02%	2.46%	1.66%	57.06%	52.93%	2.65%	1.47%	57.06%
	0.13%	1.45%	7.04%	0.02%	84.16%	4.31%	2.91%	100.00%	92.77%	4.65%	2.58%	100.00%
	40.00%	45.41%	65.71%	100.00%	57.03%	55.44%	51.00%	57.06%	57.35%	56.19%	49.23%	57.06%
Male	12	107	226	0	3,902	213	172	4,632	4,245	223	164	4,632
	0.11%	0.99%	2.10%	0.00%	36.18%	1.97%	1.59%	42.94%	39.36%	2.07%	1.52%	42.94%
	0.26%	2.31%	4.88%	0.00%	84.24%	4.60%	3.71%	100.00%	91.65%	4.81%	3.54%	100.00%
	60.00%	54.59%	34.29%	0.00%	42.97%	44.56%	49.00%	42.94%	42.65%	43.81%	50.77%	42.94%
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	20	196	659	1	9,081	478	351	10,786	9,954	509	323	10,786
	0.19%	1.82%	6.11%	0.01%	84.19%	4.43%	3.25%	100.00%	92.29%	4.72%	2.99%	100.00%
	0.19%	1.82%	6.11%	0.01%	84.19%	4.43%	3.25%	100.00%	92.29%	4.72%	2.99%	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	286	286	1,082
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.19%	56.19%	10.03%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.58%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.19%	56.19%	58.08%
Male	0	0	0	0	0	0	223	223	781
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.81%	43.81%	7.24%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	16.86%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.81%	43.81%	41.92%
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	0	0	0	0	0	0	509	509	1,863
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.27%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.27%
	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 15A

Number of Protocols with Enrollment Data: **16**

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	126	23	77	31	996	5	1,258	257
	3.71%	**0.68%**	**2.27%**	**0.91%**	**29.34%**	**0.15%**	**37.05%**	**7.57%**
	10.02%	*1.83%*	*6.12%*	*2.46%*	*79.17%*	*0.40%*	*100.00%*	*20.43%*
	71.59%	35.38%	33.92%	38.27%	35.19%	31.25%	37.05%	46.81%
Male	50	42	150	50	1,834	11	2,137	292
	1.47%	**1.24%**	**4.42%**	**1.47%**	**54.02%**	**0.32%**	**62.95%**	**8.60%**
	2.34%	*1.97%*	*7.02%*	*2.34%*	*85.82%*	*0.51%*	*100.00%*	*13.66%*
	28.41%	64.62%	66.08%	61.73%	64.81%	68.75%	62.95%	53.19%
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	176	65	227	81	2,830	16	3,395	549
	5.18%	**1.91%**	**6.69%**	**2.39%**	**83.36%**	**0.47%**	**100.00%**	**16.17%**
	5.18%	*1.91%*	*6.69%*	*2.39%*	*83.36%*	*0.47%*	*100.00%*	*16.17%*
	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 females (7,412 or 52.3%) than males (6,769 or 47.7%) are enrolled in aggregate Phase III Domestic extramural research protocols.
More minority females (1,339 or 55.5%) than minority males (1,073 or 44.5%) are enrolled in aggregate Phase III Domestic extramural research protocols.

Approximately 17% (2,412) of participants in aggregate PhaseIII Domestic extramural research (14,181) are classified as U.S. minorities.

Race: White doesn’t rank as a top racial category.
Largest identified racial minority group is Black or African American at 6.11 % following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 6.7% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.01%.
According to the 1977 OMB standards, the smallest identified racial minority group is Asian/ Pacific Islander at 1.1%.

Ethnicity:
4.72% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is Unknow at 100%
Of the 509 participants, 56.2% are women and 43.8% are men.
2.4% of participants identified as Hispanic according to the 1977 OMB standards.

Table 16A. FOREIGN Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**1,788,820**	**1,618,146**		**90.46%**
%	**52.53%**	**52.42%**		
Males	**1,605,628**	**1,464,176**		**91.19%**
%	**47.15%**	**47.43%**		
Unknown	**10,781**	**4,859**		**45.07%**
%	**0.32%**	**0.16%**		
TOTAL	**3,405,229**	**3,087,181**	**90.66%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 464

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

Number of Protocols with Enrollment Data: 434

	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	17,120	1,322,684	111,823	1,576	131,689	71,659	86,056	1,742,607	1,537,817	142,023	62,767	1,742,607
	0.52%	**40.06%**	**3.39%**	**0.05%**	**3.99%**	**2.17%**	**2.61%**	**52.77%**	**46.57%**	**4.30%**	**1.90%**	**52.77%**
	0.98%	*75.90%*	*6.42%*	*0.09%*	*7.56%*	*4.11%*	*4.94%*	*100.00%*	*88.25%*	*8.15%*	*3.60%*	*100.00%*
	56.10%	52.56%	51.03%	47.50%	53.96%	50.01%	59.31%	52.77%	52.59%	55.10%	52.15%	52.77%
Male	13,295	1,193,722	105,226	1,740	110,891	71,494	55,659	1,552,027	1,384,103	114,318	53,606	1,552,027
	0.40%	**36.15%**	**3.19%**	**0.05%**	**3.36%**	**2.17%**	1.69%	**47.00%**	**41.92%**	**3.46%**	**1.62%**	**47.00%**
	0.86%	*76.91%*	*6.78%*	*0.11%*	*7.14%*	*4.61%*	3.59%	*100.00%*	*89.18%*	*7.37%*	*3.45%*	*100.00%*
	43.56%	47.43%	48.02%	52.44%	45.44%	49.90%	38.36%	47.00%	47.34%	44.35%	44.54%	47.00%
Unknown	104	183	2,091	2	1477	126	3,390	7,373	1,965	1,415	3,993	7,373
	0.00%	**0.01%**	**0.06%**	0.00%	**0.04%**	**0.00%**	*0.10%*	**0.22%**	**0.06%**	**0.04%**	**0.12%**	**0.22%**
	1.41%	*2.48%*	*28.36%*	*0.03%*	*20.03%*	*1.71%*	*45.98%*	*100.00%*	*26.65%*	*19.19%*	*54.16%*	*100.00%*
	0.34%	0.01%	0.95%	0.06%	0.61%	0.09%	2.34%	0.22%	0.07%	0.55%	3.32%	0.22%
Total	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
	0.92%	**76.21%**	**6.64%**	**0.10%**	**7.39%**	**4.34%**	**4.39%**	**100.00%**	**88.55%**	**7.81%**	**3.65%**	**100.00%**
	0.92%	*76.21%*	*6.64%*	*0.10%*	*7.39%*	*4.34%*	*4.39%*	*100.00%*	*88.55%*	*7.81%*	*3.65%*	*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	16,665	54	996	294	20,359	68,345	35,310	142,023	1,580,531
	6.47%	**0.02%**	**0.39%**	**0.22%**	**7.90%**	**26.52%**	**13.70%**	**55.10%**	**47.87%**
	11.73%	*0.04%*	*0.70%*	*0.43%*	*14.34%*	*48.12%*	*24.86%*	*100.00%*	*90.70%*
	0.00%	0.00%	0.00%	0.00%	0.00%	50.13%	75.84%	55.10%	52.65%
Male	12,816	46	846	394	22,158	67,981	10,077	114,318	1,417,712
	4.97%	**0.02%**	**0.33%**	**0.29%**	**8.60%**	**26.37%**	**3.91%**	**44.35%**	**42.93%**
	11.21%	*0.04%*	*0.74%*	*0.58%*	*19.38%*	*59.47%*	*8.81%*	*100.00%*	*91.35%*
	0.00%	0.00%	0.00%	0.00%	0.00%	49.87%	21.64%	44.35%	47.22%
Unknown	95	1	0	0	148	0	1,171	1,415	3,825
	0.04%	**0.00%**	**0.00%**	**0.00%**	**0.06%**	**0.00%**	**0.45%**	**0.55%**	**0.12%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*51.88%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	2.52%	0.55%	0.13%
TOTAL	29,576	101	1,842	688	42,665	136,326	46,558	257,756	3,002,068
	11.47%	**0.04%**	**0.71%**	**0.50%**	**16.55%**	**52.89%**	**18.06%**	**100.00%**	**90.92%**
	11.47%	*0.04%*	*0.71%*	*0.50%*	*16.55%*	*52.89%*	*18.06%*	*100.00%*	*90.92%*
	0.00%	0.00%	0.00%	0.00%	0.00%	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: **30**

	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	20	35,535	369	1,691	7,963	635	46,213	37,615
	0.02%	**34.43%**	**0.36%**	**1.64%**	**7.71%**	**0.62%**	**44.77%**	**36.44%**
	0.04%	*76.89%*	*0.80%*	*3.66%*	*17.23%*	*1.37%*	*100.00%*	*81.39%*
	0.00%	44.37%	50.97%	39.47%	48.68%	36.26%	44.77%	44.19%
Male	0	44,510	355	1,599	6,023	1,114	53,601	46,464
	0.00%	**43.12%**	**0.34%**	**1.55%**	**5.83%**	**1.08%**	**51.93%**	**45.01%**
	0.00%	*83.04%*	*0.66%*	*2.98%*	*11.24%*	*2.08%*	*100.00%*	*86.68%*
	0.00%	55.58%	49.03%	37.32%	36.82%	63.62%	51.93%	54.59%
Unknown	0	40	0	994	2,372	2	3,408	1,034
	0.000%	**0.04%**	**0.00%**	**0.96%**	**2.30%**	**0.00%**	**3.30%**	**1.00%**
	0.00%	*1.17%*	*0.00%*	*29.17%*	*69.60%*	*0.06%*	*100.00%*	*30.34%*
	0.00%	0.05%	0.00%	23.20%	14.50%	0.11%	3.30%	1.21%
Total	20	80,085	724	4,284	16,358	1,751	103,222	85,113
	0.02%	**77.59%**	**0.70%**	**4.15%**	**15.85%**	**1.70%**	**100.00%**	**82.46%**
	0.02%	*77.59%*	*0.70%*	*4.15%*	*15.85%*	*1.70%*	*100.00%*	*82.46%*
	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 females (1,788,820 or 52.53%) than males (1,605,628 or 47.15%) are enrolled in aggregate Foreign extramural and intramural research protocols.

More minority females (1,618,146 or 52.42%) than minority males (1464,176 or 47.43 %) are enrolled in aggregate Foreign extramural and intramural research protocols.

Approximately 90.66% (3,087,181) of participants in aggregate Foreign extramural and intramural research (3,405,229) are classified as U.S. minorities.

Race: White doesn’t rank as a top racial category.
Largest identified racial minority group is Asian at 76.21% and Black or African American at 6.64% following the 1997 OMB standards.
Largest identified racial minority group is Asian/ Pacific Islander at 77.59% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.1%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/ Alaska Native at 0.02%.

Ethnicity:
7.81% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:

Largest identified racial group is More Than One Race at 52.89%(2nd hightest category is Unknown at 18.06%)
Smallest identified racial group is Asian at 0.04%.
Of the 257,756 participants, 55.10% are women and 44.35% are men.

4.15% of participants identified as Hispanic according to the 1977 OMB standards.

Table 17A. FOREIGN Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**1,565,124**	**1,474,261**		**94.19%**
%	**51.32%**	**51.21%**		
Males	**1,479,765**	**1,400,741**		**94.66%**
%	**48.52%**	**48.66%**		
Unknown	**5,120**	**3,824**		**74.69%**
%	**0.17%**	**0.13%**		
TOTAL	**3,050,009**	**2,878,826**	**94.39%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **384**

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

Number of Protocols with Enrollment Data: **370**

	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	17,118	1,234,924	109,826	1,574	61,559	69,986	67,387	1,562,374	1,385,916	124,867	51,591	1,562,374
	0.56%	**40.57%**	**3.61%**	**0.05%**	**2.02%**	**2.30%**	**2.21%**	**51.32%**	**45.53%**	**4.10%**	**1.69%**	**51.32%**
	1.10%	*79.04%*	*7.03%*	*0.10%*	*3.94%*	*4.48%*	*4.31%*	*100.00%*	*88.71%*	*7.99%*	*3.30%*	*100.00%*
	56.09%	51.11%	51.22%	47.47%	51.82%	49.91%	55.89%	51.32%	51.19%	52.41%	52.32%	51.32%
Male	13,295	1,181,277	102,515	1,740	55,875	70,126	51,939	1,476,767	1,319,633	111,970	45,164	1,476,767
	0.44%	**38.80%**	**3.37%**	**0.06%**	**1.84%**	**2.30%**	1.71%	**48.51%**	**43.35%**	**3.68%**	**1.48%**	**48.51%**
	0.90%	*79.99%*	*6.94%*	*0.12%*	*3.78%*	*4.75%*	3.52%	*100.00%*	*89.36%*	*7.58%*	*3.06%*	*100.00%*
	43.57%	48.89%	47.81%	52.47%	47.03%	50.00%	43.08%	48.51%	48.74%	47.00%	45.80%	48.51%
Unknown	104	182	2,091	2	1,364	126	1,249	5,118	1,851	1,415	1,852	5,118
	0.00%	**0.01%**	**0.07%**	0.00%	**0.04%**	**0.00%**	*0.04%*	**0.17%**	**0.06%**	**0.05%**	**0.06%**	**0.17%**
	2.03%	*3.56%*	*40.86%*	0.04%	*26.65%*	*2.46%*	*24.40%*	*100.00%*	*36.17%*	*27.65%*	*36.19%*	*100.00%*
	0.34%	0.01%	0.98%	0.06%	1.15%	0.09%	1.04%	0.17%	0.07%	0.59%	1.88%	0.17%
Total	30,517	2,416,383	214,432	3,316	118,798	140,238	120,575	3,044,259	2,707,400	238,252	98,607	3,044,259
	1.00%	**79.38%**	**7.04%**	**0.11%**	**3.90%**	**4.61%**	**3.96%**	**100.00%**	**88.93%**	**7.83%**	**3.24%**	**100.00%**
	1.00%	*79.38%*	*7.04%*	*0.11%*	*3.90%*	*4.61%*	*3.96%*	*100.00%*	*88.93%*	*7.83%*	*3.24%*	*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	16,663	54	314	293	20,166	66,798	20,579	124,867	1,474,173
	6.99%	**0.02%**	**0.13%**	**0.22%**	**8.46%**	**28.04%**	**8.64%**	**52.41%**	**48.42%**
	13.34%	*0.04%*	*0.25%*	*0.44%*	*16.15%*	*53.50%*	*16.48%*	*100.00%*	*94.35%*
	56.34%	53.47%	50.81%	0.00%	47.62%	50.03%	65.49%	52.41%	51.21%
Male	12,816	46	304	394	22,039	66,708	9,663	111,970	1,400,655
	5.38%	**0.02%**	**0.13%**	**0.30%**	**9.25%**	**28.00%**	**4.06%**	**47.00%**	**46.01%**
	11.45%	*0.04%*	*0.27%*	*0.59%*	*19.68%*	*59.58%*	*8.63%*	*100.00%*	*94.85%*
	43.34%	45.54%	49.19%	0.00%	52.05%	49.97%	30.75%	47.00%	48.66%
Unknown	95	1	0	0	140	0	1,179	1,415	3,824
	0.04%	**0.00%**	**0.00%**	**0.00%**	**0.06%**	**0.00%**	**0.49%**	**0.59%**	**0.13%**
	6.71%	*0.07%*	*0.00%*	*0.00%*	*9.89%*	*0.00%*	*83.32%*	*100.00%*	*74.72%*
	0.32%	0.99%	0.00%	0.00%	0.33%	0.00%	3.75%	0.59%	0.13%
TOTAL	29,574	101	618	687	42,345	133,506	31,421	238,252	2,878,652
	12.41%	**0.04%**	**0.26%**	**0.29%**	**17.77%**	**56.04%**	**13.19%**	**100.00%**	**94.56%**
	12.41%	*0.04%*	*0.26%*	*0.51%*	*17.77%*	*56.04%*	*13.19%*	*100.00%*	*94.56%*
	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 17A

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

Number of Protocols with Enrollment Data: **14**

	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	17	42	21	8	2,512	150	2,750	88
	0.30%	**0.73%**	**0.37%**	**0.14%**	**43.69%**	**2.61%**	**47.83%**	**1.53%**
	0.62%	*1.53%*	*0.76%*	*0.29%*	*91.35%*	*5.45%*	*100.00%*	*3.20%*
	0.00%	73.68%	34.43%	20.51%	52.36%	19.28%	47.83%	50.57%
Male	0	15	40	31	2,286	626	2,998	86
	0.00%	**0.26%**	**0.70%**	**0.54%**	**39.76%**	**10.89%**	**52.14%**	**1.50%**
	0.00%	*0.50%*	*1.33%*	*1.03%*	*76.25%*	*20.88%*	*100.00%*	*2.87%*
	0.00%	26.32%	65.57%	79.49%	47.64%	80.46%	52.14%	49.43%
Unknown	0	0	0	0	0	2	2	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.03%**	**0.03%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.26%	0.03%	0.00%
Total	17	57	61	39	4,798	778	5,750	174
	0.30%	**0.99%**	**1.06%**	**0.68%**	**83.44%**	**13.53%**	**100.00%**	**3.03%**
	0.30%	*0.99%*	*1.06%*	*0.68%*	*83.44%*	*13.53%*	*100.00%*	*3.03%*
	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 females (1,565,124 or 51.3%) than males (1,479,765 or 48.5%) are enrolled in aggregate foreign extramural research protocols.
More minority females (1,474,261 or 51.2%) than minority males (1,400,741 or 48.7%) are enrolled in aggregate foreign extramural research protocols.

Approximately 94.4% (2,878,826) of participants in aggregate foreign extramural research (3,050,009) are classified as U.S. minorities.

Race: White doesn't rank as a top racial category.
Largest identified racial minority group is Asians at 79% following the 1997 OMB standards.
Largest identified racial minority group is Black or African American at 1.06% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.1%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/ Alaska Native at 0.3%.

Ethnicity:
7.8% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is More Than One Race at 56.04% (2nd hightest category is White at 17.8%)
Smallest identified racial group is Asian at 0.04%.
Of the 238,252 participants, 52.41% are women and 47% are men.
0.7% of participants identified as Hispanic according to the 1977 OMB standards.

Table 18A. FOREIGN Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**223,696**	**143,883**		**64.32%**
%	**62.97%**	**69.06%**		
Males	**126,863**	**64,431**		**50.79%**
%	**35.71%**	**30.92%**		
Unknown	**4,661**	**41**		**0.88%**
%	**1.31%**	**0.02%**		
TOTAL	**355,220**	**208,355**	**58.66%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **80**

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

Number of Protocols with Enrollment Data: **64**

	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	2	87,760	1,997	2	70,130	1,673	18,669	180,233	151,901	17,156	11,176	180,233
	0.00%	**34.05%**	**0.77%**	**0.00%**	**27.21%**	**0.65%**	**7.24%**	**69.93%**	**58.93%**	**6.66%**	**4.34%**	**69.93%**
	0.00%	*48.69%*	*1.11%*	*0.00%*	*38.91%*	*0.93%*	*10.36%*	*100.00%*	*84.28%*	*9.52%*	*6.20%*	*100.00%*
	100.00%	87.58%	42.42%	100.00%	55.99%	55.01%	76.11%	69.93%	70.17%	87.96%	51.36%	69.93%
Male	0	12,445	2,711	0	55,016	1,368	3,720	75,260	64,470	2,348	8,442	75,260
	0.00%	**4.83%**	**1.05%**	**0.00%**	**21.34%**	**0.53%**	1.44%	**29.20%**	**25.01%**	**0.91%**	**3.28%**	**29.20%**
	0.00%	*16.54%*	*3.60%*	*0.00%*	*73.10%*	*1.82%*	4.94%	*100.00%*	*85.66%*	*3.12%*	*11.22%*	*100.00%*
	0.00%	12.42%	57.58%	0.00%	43.92%	44.99%	15.17%	29.20%	29.78%	12.04%	38.80%	29.20%
Unknown	0	1	0	0	113	0	2,141	2,255	114	0	2,141	2,255
	0.00%	**0.00%**	**0.00%**	0.00%	**0.04%**	**0.00%**	***0.83%***	**0.87%**	**0.04%**	**0.00%**	**0.83%**	**0.87%**
	0.00%	*0.04%*	*0.00%*	0.00%	*5.01%*	*0.00%*	*94.94%*	*100.00%*	*5.06%*	*0.00%*	*94.94%*	*100.00%*
	0.00%	0.00%	0.00%	0.00%	0.09%	0.00%	8.73%	0.87%	0.05%	0.00%	9.84%	0.87%
Total	2	100,206	4,708	2	125,259	3,041	24,530	257,748	216,485	19,504	21,759	257,748
	0.00%	**38.88%**	**1.83%**	**0.00%**	**48.60%**	**1.18%**	**9.52%**	**100.00%**	**83.99%**	**7.57%**	**8.44%**	**100.00%**
	0.00%	*38.88%*	*1.83%*	*0.00%*	*48.60%*	*1.18%*	*9.52%*	*100.00%*	*83.99%*	*7.57%*	*8.44%*	*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	4	0	682	1	193	1,547	14,729	17,156	106,356
	0.02%	**0.00%**	**3.50%**	**0.04%**	**0.99%**	**7.93%**	**75.52%**	**87.96%**	**41.26%**
	0.02%	*0.00%*	*3.98%*	*0.06%*	*1.12%*	*9.02%*	*85.85%*	*100.00%*	*59.01%*
	100.00%	0.00%	55.54%	0.00%	62.66%	54.86%	97.27%	87.96%	86.18%
Male	0	0	546	0	115	1,273	414	2,348	17,053
	0.00%	**0.00%**	**2.80%**	**0.00%**	**0.59%**	**6.53%**	**2.12%**	**12.04%**	**6.62%**
	0.00%	*0.00%*	*23.25%*	*0.00%*	*4.90%*	*54.22%*	*17.63%*	*100.00%*	*22.66%*
	0.00%	0.00%	44.46%	0.00%	37.34%	45.14%	2.73%	12.04%	13.82%
Unknown	0	0	0	0	0	0	0	0	1
	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%*	*0.04%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	4	0	1,228	1	308	2,820	15,143	19,504	123,410
	0.02%	**0.00%**	**6.30%**	**0.01%**	**1.58%**	**14.46%**	**77.64%**	**100.00%**	**47.88%**
	0.02%	*0.00%*	*6.30%*	*0.04%*	*1.58%*	*14.46%*	*77.64%*	*100.00%*	*47.88%*
	100.00%	0.00%	100.00%	0.00%	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: **16**

	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	3	35,493	348	1,683	5,451	485	43,463	37,527
	0.00%	**36.41%**	**0.36%**	**1.73%**	**5.59%**	**0.50%**	**44.59%**	**38.50%**
	0.01%	*81.66%*	*0.80%*	*3.87%*	*12.54%*	*1.12%*	*100.00%*	*86.34%*
	0.00%	43.80%	52.49%	51.77%	53.54%	20.68%	44.59%	44.18%
Male	0	45,495	315	1,568	3,737	488	51,603	47,378
	0.00%	**46.67%**	**0.32%**	**1.61%**	**3.83%**	**0.50%**	**52.94%**	**48.61%**
	0.00%	*88.16%*	*0.61%*	*3.04%*	*7.24%*	*0.95%*	*100.00%*	*91.81%*
	0.00%	56.15%	47.51%	48.23%	36.70%	20.81%	52.94%	55.77%
Unknown	0	40	0	0	994	1,372	2,406	40
	0.000%	**0.04%**	**0.00%**	**0.00%**	**1.02%**	**1.41%**	**2.47%**	**0.04%**
	0.00%	*1.66%*	*0.00%*	*0.00%*	*41.31%*	*57.02%*	*100.00%*	*1.66%*
	0.00%	0.05%	0.00%	0.00%	9.76%	58.51%	2.47%	0.05%
Total	3	81,028	663	3,251	10,182	2,345	97,472	84,945
	0.00%	**83.13%**	**0.68%**	**3.34%**	**10.45%**	**2.41%**	**100.00%**	**87.15%**
	0.00%	*83.13%*	*0.68%*	*3.34%*	*10.45%*	*2.41%*	*100.00%*	*87.15%*
	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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:
More females (223,696 or 62.97%) than males (126,863 or 35.7%) are enrolled in aggregate foreign intramural research protocols.
More minority females (143.883 or 69.06%) than males (64,431 or 30.9%) are enrolled in aggregate foreign intramural research protocols.

Approximately 58.9% (208,355) of participants in aggregate foreign intramural research (355,220) are classified as U.S. minorities.

Race: White doesn't rank as a top racial category.
Largest identified racial minority group is Asians at 38.9% following the 1997 OMB standards.
Largest identified racial minority group is Asian/Pacific Islanders at 83.1% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native and Hawaiian/Pacific Islander at 0%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 0.0%.

Ethnicity:
7.57% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:

Largest identified racial group is Unknown /Other at 77.7 % (2nd hightest category is More Than One Race at 14.5%)
Smallest identified racial group is Aian at 0%.
Of the 19.504 participants,87.9% are women and 12% are men.

3.34% of participants identified as Hispanic according to the 1977 OMB standards.

Table 19A. FOREIGN Aggregate Enrollment Data for Phase III Extramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**46,022**	**38,939**		**84.61%**
%	**56.24%**	**55.77%**		
Males	**34,636**	**30,582**		**88.30%**
%	**42.32%**	**43.80%**		
Unknown	**1,180**	**299**		**25.34%**
%	**1.44%**	**0.43%**		
TOTAL	**81,838**	**69,820**	**85.31%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **56**

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

Number of Protocols with Enrollment Data: **49**

	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	1,064	13,456	13,998	3	5,218	22	9,766	43,527	31,451	11,452	624	43,527
	1.39%	**17.58%**	**18.29%**	**0.00%**	**6.82%**	**0.03%**	**12.76%**	**56.88%**	**41.10%**	**14.96%**	**0.82%**	**56.88%**
	2.44%	*30.91%*	*32.16%*	*0.01%*	*11.99%*	*0.05%*	*22.44%*	*100.00%*	*72.26%*	*26.31%*	*1.43%*	*100.00%*
	55.82%	49.75%	51.07%	60.00%	64.48%	13.02%	82.10%	56.88%	51.93%	75.12%	87.27%	56.88%
Male	837	13,553	13,216	1	2,015	105	2,094	31,821	28,042	3,775	4	31,821
	1.09%	**17.71%**	**17.27%**	**0.00%**	**2.63%**	**0.14%**	2.74%	**41.58%**	**36.64%**	**4.93%**	**0.01%**	**41.58%**
	2.63%	*42.59%*	*41.53%*	*0.00%*	*6.33%*	*0.33%*	6.58%	*100.00%*	*88.12%*	*11.86%*	*0.01%*	*100.00%*
	43.91%	50.11%	48.22%	20.00%	24.90%	62.13%	17.60%	41.58%	46.30%	24.76%	0.56%	41.58%
Unknown	5	39	196	1	860	42	35	1,178	1,074	17	87	1,178
	0.01%	**0.05%**	**0.26%**	0.00%	**1.12%**	**0.05%**	*0.05%*	**1.54%**	**1.40%**	**0.02%**	**0.11%**	**1.54%**
	0.42%	*3.31%*	*16.64%*	0.08%	*73.01%*	*3.57%*	*2.97%*	*100.00%*	*91.17%*	*1.44%*	*7.39%*	*100.00%*
	0.26%	0.14%	0.72%	20.00%	10.63%	24.85%	0.29%	1.54%	1.77%	0.11%	12.17%	1.54%
Total	1,906	27,048	27,410	5	8,093	169	11,895	76,526	60,567	15,244	715	76,526
	2.49%	**35.34%**	**35.82%**	**0.01%**	**10.58%**	**0.22%**	**15.54%**	**100.00%**	**79.15%**	**19.92%**	**0.93%**	**100.00%**
	2.49%	*35.34%*	*35.82%*	*0.01%*	*10.58%*	*0.22%*	*15.54%*	*100.00%*	*79.15%*	*19.92%*	*0.93%*	*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	1,014	1	108	0	1,256	1	9,072	11,452	38,871
	6.65%	**0.01%**	**0.71%**	**0.00%**	**8.24%**	**0.01%**	**59.51%**	**75.12%**	**50.79%**
	8.85%	*0.01%*	*0.94%*	*0.00%*	*10.97%*	*0.01%*	*79.22%*	*100.00%*	*89.30%*
	54.84%	33.33%	50.70%	0.00%	94.58%	100.00%	76.56%	75.12%	55.76%
Male	835	1	105	0	59	0	2,775	3,775	30,546
	5.48%	**0.01%**	**0.69%**	**0.00%**	**0.39%**	**0.00%**	**18.20%**	**24.76%**	**39.92%**
	22.12%	*0.03%*	*2.78%*	*0.00%*	*1.56%*	*0.00%*	*73.51%*	*100.00%*	*95.99%*
	45.16%	33.33%	49.30%	0.00%	4.44%	0.00%	23.42%	24.76%	43.81%
Unknown	0	1	0	0	13	0	3	17	299
	0.00%	**0.01%**	**0.00%**	**0.00%**	**0.09%**	**0.00%**	**0.02%**	**0.11%**	**0.39%**
	0.00%	*5.88%*	*0.00%*	*0.00%*	*76.47%*	*0.00%*	*17.65%*	*100.00%*	*25.38%*
	0.00%	33.33%	0.00%	0.00%	0.98%	0.00%	0.03%	0.11%	0.43%
TOTAL	1,849	3	213	0	1,328	1	11,850	15,244	69,716
	12.13%	**0.02%**	**1.40%**	**0.00%**	**8.71%**	**0.01%**	**77.74%**	**100.00%**	**91.10%**
	12.13%	*0.02%*	*1.40%*	*0.00%*	*8.71%*	*0.01%*	*77.74%*	*100.00%*	*91.10%*
	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: **7**

	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	16	34	13	5	2,327	100	2,495	68
	0.30%	**0.64%**	**0.24%**	**0.09%**	**43.81%**	**1.88%**	**46.97%**	**1.28%**
	0.64%	*1.36%*	*0.52%*	*0.20%*	*93.27%*	*4.01%*	*100.00%*	*2.73%*
	0.00%	73.91%	43.33%	41.67%	51.33%	14.81%	46.97%	65.38%
Male	0	12	17	7	2,206	573	2,815	36
	0.00%	**0.23%**	**0.32%**	**0.13%**	**41.53%**	**10.79%**	**52.99%**	**0.68%**
	0.00%	*0.43%*	*0.60%*	*0.25%*	*78.37%*	*20.36%*	*100.00%*	*1.28%*
	0.00%	26.09%	56.67%	58.33%	48.67%	84.89%	52.99%	34.62%
Unknown	0	0	0	0	0	2	2	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.04%**	**0.04%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.30%	0.04%	0.00%
Total	16	46	30	12	4,533	675	5,312	104
	0.30%	**0.87%**	**0.56%**	**0.23%**	**85.34%**	**12.71%**	**100.00%**	**1.96%**
	0.30%	*0.87%*	*0.56%*	*0.23%*	*85.34%*	*12.71%*	*100.00%*	*1.96%*
	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 females (46,022 or 56.2%) than males (34,636 or 42.3%) are enrolled in aggregate Phase III foreign extramural research protocols.
More minority females (38,939 or 55.8%) than minority males (30,582 or 43.8%) are enrolled in aggregate Phase III foreign extramural research protocols.

Approximately 85.3% (69,820) of participants in aggregate PhaseIII foreign extramural research (81,838) are classified as U.S. minorities.

Race: White doesn't rank as a top racial category.
Largest identified racial minority group is Black or African Americanat 35.8 % following the 1997 OMB standards.
Largest identified racial minority group is Asian/Pacific Islanders at0.87% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0%.
According to the 1977 OMB standards, the smallest identified racial minority group is Hispanic at 0.23%.

Ethnicity:
19.92% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
    Largest identified racial group is Unknown at 77.74% (2nd hightest category is American Indian/Alaska Native at 12.13%)
    Smallest identified racial group is Hawaiian/Pacific Islander at 0%.
    Of the 15,244 participants, 75% are women and 24% are men.
0.23% of participants identified as Hispanic according to the 1977 OMB standards.

Table 20A. FOREIGN Aggregate Enrollment Data for Phase III Intramural Research Protocols Funded in FY2005 and Reported in FY2006: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**9,577**	**8,270**		**86.35%**
%	**55.37%**	**56.67%**		
Males	**7,718**	**6,322**		**81.91%**
%	**44.63%**	**43.33%**		
Unknown	**0**	**0**		**0.00%**
%	**0.00%**	**0.00%**		
TOTAL	**17,295**	**14,592**	**84.37%**	
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: **3**

	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	60	0	0	0	3,547	3,607	60	2,240	1,307	3,607
	0.00%	**0.00%**	**1.19%**	**0.00%**	**0.00%**	**0.00%**	**70.29%**	**71.48%**	**1.19%**	**44.39%**	**25.90%**	**71.48%**
	0.00%	*0.00%*	*1.66%*	*0.00%*	*0.00%*	*0.00%*	*98.34%*	*100.00%*	*1.66%*	*62.10%*	*36.24%*	*100.00%*
	0.00%	0.00%	58.25%	0.00%	0.00%	0.00%	71.76%	71.48%	58.25%	100.00%	48.35%	71.48%
Male	0	0	43	0	0	0	1,396	1,439	43	0	1,396	1,439
	0.00%	**0.00%**	**0.85%**	**0.00%**	**0.00%**	**0.00%**	27.67%	**28.52%**	**0.85%**	**0.00%**	**27.67%**	**28.52%**
	0.00%	*0.00%*	*2.99%*	*0.00%*	*0.00%*	*0.00%*	97.01%	*100.00%*	*2.99%*	*0.00%*	*97.01%*	*100.00%*
	0.00%	0.00%	41.75%	0.00%	0.00%	0.00%	28.24%	28.52%	41.75%	0.00%	51.65%	28.52%
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	103	0	0	0	4,943	5,046	103	2,240	2,703	5,046
	0.00%	**0.00%**	**2.04%**	**0.00%**	**0.00%**	**0.00%**	**97.96%**	**100.00%**	**2.04%**	**44.39%**	**53.57%**	**100.00%**
	0.00%	*0.00%*	*2.04%*	*0.00%*	*0.00%*	*0.00%*	*97.96%*	*100.00%*	*2.04%*	*44.39%*	*53.57%*	*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	2,240	2,240	2,300
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**100.00%**	**45.58%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*63.76%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	98.16%
Male	0	0	0	0	0	0	0	0	43
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.85%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*2.99%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	1.84%
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	0	0	0	0	0	0	2,240	2,240	2,343
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**100.00%**	**46.43%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*46.43%*
	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: **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	5,970	0	0	0	0	5,970	5,970
	0.00%	**48.74%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**48.74%**	**48.74%**
	0.00%	*100.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*
	0.00%	48.74%	0.00%	0.00%	0.00%	0.00%	48.74%	48.74%
Male	0	6,279	0	0	0	0	6,279	6,279
	0.00%	**51.26%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**51.26%**	**51.26%**
	0.00%	*100.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*
	0.00%	51.26%	0.00%	0.00%	0.00%	0.00%	51.26%	51.26%
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	0	12,249	0	0	0	0	12,249	12,249
	0.00%	**100.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**100.00%**
	0.00%	*100.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*
	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 females (9,577 or 55.4%) than males (7,718 or 44.6%) are enrolled in aggregate Phase III foreign intamural research protocols.
More minority females (8,270or 56.7%) than minority males (6,322 or 43.3%) are enrolled in aggregate PhaseIII foreign intramural research protocols.

Approximately 84.4% (14,592) of participants in aggregate Phase III foreign intramural research (17,295) are classified as U.S. minorities.

Race: White doesn’t rank as a top racial category.
Largest identified racial minority group is Black or African American at 2.04% following the 1997 OMB standards.
Largest identified racial minority group is Asian/Pacific Islanders at 100% following the 1977 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native, Asian, Hawaiian/Pacific Islander at 0%.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native, Black or African American, Hispanic at 0.04%.

Ethnicity:
44.4% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethcnicity as Hispanic/Latino:
Largest identified racial group is Unknow/Other at 100%
Of the 2,240 participants, 100% are women
0% of participants identified as Hispanic according to the 1977 OMB standards.