

Department of Health and Human Services
National Institutes of Health

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

Comprehensive Report: Tracking of Human Subjects Research
As Reported in Fiscal Year 2009 and Fiscal Year 2010

2011 Report

Table of Contents

	<u>Page</u>
<u>Historical Summary and Current Activities</u>	
Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research	1-8
<u>FY2009 and FY2010 Data Analyses</u>	
Data Analyses Report, Executive Summary Data Tables and Fifteen-Year Trend Tables	1-66
<u>NIH Wide Clinical Research Performed in FY2008-2009 and Reported in FY2009-2010</u>	
Table 1	Summary of NIH Clinical Research Reported in FY2009: Total Number of Protocols and Enrollment by Sex and Domestic versus Foreign Protocols..... 19
Table 2	Summary of NIH Clinical Research Reported in FY2010: Total Number of Protocols and Enrollment by Sex and Domestic versus Foreign Protocols..... 20
Table 3	Summary of NIH Phase III Clinical Research Reported in FY2009: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols..... 21
Table 4	Aggregate Enrollment Data for Extramural and Intramural Phase III Research Funded in FY2008 and Reported in FY2009: Percent Analysis..... 22
Table 5	Summary of NIH Phase III Clinical Research Reported in FY2010: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols 24
Table 6	Aggregate Enrollment Data for Extramural and Intramural Phase III Research Funded in FY2009 and Reported in FY2010: Percent Analysis 25
Table 7	Sixteen-Year Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2010 27
Table 8	Overview of NIH Extramural and Intramural Clinical Research Reported in FY2009: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols.... 34
Table 9	Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis..... 36
Table 10	Overview of NIH Extramural and Intramural Clinical Research Reported in FY2010: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols.... 38
Table 11	Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis 40
Table 12	Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis 42
Table 13	Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis 44

Table 14	Overview of NIH Phase III Extramural and Intramural Clinical Research Reported in FY2009: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols	46
Table 15	Aggregate Enrollment Data for Extramural Phase III Research Funded in FY2008 and Reported in FY2009: Percent Analysis.....	48
Table 16	Overview of NIH Phase III Extramural and Intramural Clinical Research Reported in FY2010: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols	50
Table 17	Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis	52
Table 18	Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis.....	54
Table 19	Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis.....	56
Table 20	Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis.....	58
Table 21	Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis	60
Table 22	NIH Sixteen-Year Trends for Protocol and Enrollment Data: 1995-2010*	62
Table 23	NIH Sixteen-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2010	64

Appendices

Appendix A	Historical Narrative on the Implementation of the NIH Inclusion Policy
Appendix B	Explanation of Gender and Minority Codes
Appendix C	Internet Homepage: Inclusion of Women and Minorities Policy Implementation
Appendix D	NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001
Appendix E	NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research
Appendix F	NIH Inclusion Tables for Target and Enrollment Data
Appendix G	FY2010 Aggregate Extramural and Intramural Data Tables

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

Historical Perspective

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 1985¹, 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 1987². 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)³ entitled *Women and Minorities as Subjects in Clinical Research*. In 1994, NIH revised its inclusion policy to be in compliance with the statutory language. 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*⁴ 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 and adherence to the revised guidelines across the NIH included NIH-wide training of staff and Institutional Review Board chairs in 1994. An NIH Tracking and Inclusion Committee was established made up of representatives of the directors of each of the Institutes and Centers (ICs). This trans-NIH committee, convened by the Office of Research on Women's Health (ORWH) and co-chaired with a senior IC official, met 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 NIH, ORWH coordinated the development of 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.

In addition, 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. Training was especially important in light of 1990 General Accounting Office (GAO) findings that NIH's initial

policy on inclusion was inconsistently applied and had not been well communicated or understood within NIH or in the research community.

GAO Report, May 2000: Recommendations and Actions Taken

Following a Congressional request for an assessment of NIH progress in implementing the 1994 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*.⁵ It concluded that in the past decade, NIH had 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:

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

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

- **Updating the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research**⁶ 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 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 enrollment annually and results of analyses, as appropriate.
- **Guidelines and instructions for reviewers and Scientific Review Officers (SROs) were developed** to emphasize and clarify the need to review research proposals that are classified as NIH-defined Phase III clinical trials for both inclusion requirements and issues related to analyses by sex/gender and/or race/ethnicity. Instructions were developed for the proper documentation to include in summary statements to address adherence to these policies.

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

Format Changes for Reporting Race and Ethnicity Data as of FY2002

Beginning in FY2002, NIH changed how data are reported based on the 1997 Office of Management and Budget (OMB) revisions to the 1977 Directive 15 "Race and Ethnic Standards for Federal Statistics and Administrative Reporting," which provided minimum standards for maintaining, collecting and reporting data on race and ethnicity. In October 1997, OMB published "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity; and their implementation 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, whereas 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 do not easily 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 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 data originating prior to FY 2002 data are difficult although trends can be approximated.

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

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 race, or more than one racial category.

Targeted/Planned Enrollment: Comparison of Old (1977) and New (1997) Forms

I. Old Form (1977 OMB Race/Ethnicity Categories)

Race/Ethnicity Category	Inclusion in Minority Total
American Indian/Alaska Native	X
Asian/Pacific Islander	X
Black or African American	X
Hispanic, Not White	X
White	
Unknown/Other	

II. New Form (1997 OMB Race./Ethnicity Categories)

Part A. Total Enrollment Report

Racial / Ethnic Categories	Racial or Ethnic Category	Inclusion in Minority Total
American Indian/Alaska Native	Racial	X
Asian	Racial	X
Black or African American	Racial	X
Hawaiian/Pacific Islander	Racial	X
White	Racial	
More Than One Race	Racial	X
Unknown/Other	Racial	
Racial Categories: Total of all Subjects	Racial Total*	
Hispanic or Latino	Ethnic**	
Not Hispanic or Latino	Ethnic	
Unknown (ethnicity not reported)	Ethnic	
Ethnic Categories: Total of All Subjects	Ethnic Total*	

Part B: Hispanic Enrollment Report

Racial / Ethnic Categories	Racial or Ethnic Category	Inclusion in Minority Total
American Indian/Alaska Native	Ethnic	
Asian	Ethnic	
Black or African American	Ethnic	
Hawaiian/Pacific Islander	Ethnic	
White (Hispanic)	Ethnic	X
More Than One Race	Ethnic	
Unknown/Other (Hispanic)	Ethnic	X
Racial Categories: Total of Hispanics or Latinos	Ethnic Total**	

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

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

Continuing Implementation and Monitoring Activities

The PHS 398 grant application was significantly revised to provide additional instructions concerning the Women and Minorities Inclusion Policy and the new enrollment form became mandatory as of May 10, 2005. These PHS 398 instructions are also included in the federal application form SF-424 (R&R) for NIH grants using the federal Grants.gov system (<http://era.nih.gov/ElectronicReceipt/>) including two significant changes in definitions. First, NIH requires 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. Second, NIH adopted the 1997 revisions to OMB Directive 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting", and required the revised categories to be used when reporting race and ethnic data (<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 interventions being studied affect women or members of minority groups differently than other subjects.

In FY 2007, two training sessions were developed for NIH staff involved in the management or review of clinical research studies. Approximately 300 NIH staff members attended each session in person, and additional staff participated in the training via webcast.

Communication and Outreach Efforts to the Scientific Community

NIH staff members provide outreach to the scientific community to help increase understanding of any revised inclusion policies. These training and outreach efforts improve understanding of the sex/gender and minority inclusion policy and assist investigators and NIH intramural research 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, current OMB requirements for reporting race and ethnicity data, and information for application submission, peer review, and funding. Both the Outreach Notebook and the FAQs 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 is available electronically and in hard copy, entitled "Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know!" The slide show was developed for NIH staff to assist them in working with the extramural community.

Monitoring Compliance: Extramural and Intramural Population Data Analysis

Inclusion enrollment data from each NIH Institute and Center are presented in this report in aggregate data tables, providing documentation of the monitoring of inclusion with some degree of analysis of data. Caution should be used in interpreting these figures. Conclusions that can be reasonably drawn from the data are provided.

When assessing inclusion data, enrollment figures should not be directly compared to the national census figures. The goal of the NIH policy is 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, and not to satisfy any proportional target based upon census data. The number of women, men and/or representatives of racial/ethnic subpopulations included in a particular study depends upon the scientific question addressed in the study and the prevalence among women, men and/or racial/ethnic subpopulations of the disease, disorder, or condition under investigation.

Scientific Review Groups are instructed to focus on scientific considerations when assessing the planned enrollment described in a NIH grant application for a proposed study. The Scientific Review Group (SRG) evaluates the inclusion plan and finds it 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 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 members are assured that revised inclusion plans 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 enrollment can be monitored.

NIH has monitored aggregate inclusion data for study populations through the evolving NIH automated tracking system since FY1994 and monitoring compliance with the NIH Inclusion policy is well established in all IC's. In May 2002, the NIH successfully deployed a population tracking system for monitoring inclusion data that was designed to provide easier entry of investigator-reported enrollment data and project monitoring for NIH staff. An *eRA Population Tracking User Group* consisting of representatives from several ICs provides continuous feedback related to procedures to monitor compliance.

DEFINITIONS:

Clinical Research as defined by the 1997 Report of the NIH Director's Panel on Clinical Research,

(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 continue to monitor, document, and work with grantees and contractors to ensure compliance with the inclusion policy. Program officers/staff provide technical assistance to investigators as they develop their applications and proposals throughout the application process. Review officers 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. Report of the Public Health Task Force on Women's Health: US Public Health Service, 1985. Jan-Feb; 100(1):73-106.
2. NIH Guide to Grants and Contracts, Vol. 16, No. 3, Pg 2, January 23, 1987.
3. Public Law 103-43. National Institutes of Health Revitalization Act of 1993. 42 USC 289 (a)(1).
4. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508-14513 (1994).
5. *Women's Health: NIH Has Increased Its Efforts to Include Women in Research* (GAO/HEHS-00-96, May, 2000).
6. 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:

[HYPERLINK "http://grants.nih.gov/grants/funding/women_min/women_min.htm"](http://grants.nih.gov/grants/funding/women_min/women_min.htm)

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

Revitalization Act of 1993, 42 USC 289 (a)(1): [HYPERLINK "http://grants.nih.gov/grants/guide/notice-files/not94-100.html"](http://grants.nih.gov/grants/guide/notice-files/not94-100.html) <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: [HYPERLINK "http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html"](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html)

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>

Office of Research on Women's Health Website: [HYPERLINK "http://orwh.od.nih.gov/inclusion.html"](http://orwh.od.nih.gov/inclusion.html)

<http://orwh.od.nih.gov/inclusion.html>

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

NIH AGGREGATE POPULATION DATA REPORTED IN FY2009 and FY2010

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

Analysis of aggregate NIH data on inclusion for FY2009 and FY2010 documents that substantial numbers of women and men, including minorities have been included as research subjects in NIH clinical trials, as well as other human subject research studies during these fiscal years. However, caution should be utilized to avoid over-interpreting the figures that are provided.

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

NIH CLINICAL RESEARCH: Fiscal Years 2009 and 2010

In FY2009 there were 16,689 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 11,171 protocols reported human subject participation as noted in this report's trend summary tables (table 1A). Of these, 91.9% were domestic protocols and 8.1% were foreign protocols (table 1A). Approximately 19.1 million participants were enrolled in extramural and intramural research protocols of which 93.3% were domestic participants and 6.7% were foreign participants (table 1B). Of the 19.1 million participants, 59.8% were women, 39.6% were men and 0.7% did not provide sex identification (table 1B). Further 30.2% 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 1C).

Correspondingly, in FY2010 there were 17,251 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 12,079 protocols reported human subject participation (table 2A). Of these, were 93.0% domestic protocols and 7.0% were foreign protocols (table 2A). Approximately 23.4 million participants were enrolled in extramural and intramural research protocols of which 92.1% were domestic participants and 7.9% were foreign participants (table 2B). Of the 23.3 million participants, 56.1% were women, 43.0% were men and 0.9% did not provide sex identification (table 2B). Further 32.1% of the total participants, and 28.1% of the domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity (table 2C).

Although the number of participants in all extramural and intramural clinical research increased (19.1M in FY2009 and 23.4M in FY2010), the proportion of women and men shifted slightly (59.8% F and 39.6% M in FY2009; and 56.1% F and 43.0% M in FY2010).

NIH Defined Phase III Clinical Research: FY2009 and FY2010

In FY2009 there were 662 extramural and intramural Phase III clinical research protocols, of which 630 protocols reported human subject participation (table 3A). Of these, 71.6% were domestic protocols and 28.4% were foreign protocols (table 3A). Clinical trials not included in this analysis are those studies that have just begun and have not reported enrollment data or have not begun recruiting patients. A total of 652,300 participants were enrolled in extramural and intramural Phase III research protocols of which 66.5% were domestic participants and 33.5% were foreign participants (table 3B). Of the 652,300 participants, 53.0% were women, 42.3% were men and 4.7% did not provide sex identification (table 3B). Further 44.8% of the total participants and 22.4% of domestic-protocol participants, in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity (table 3C).

Moreover, in FY2009, there were 434 extramural and intramural Phase III research protocols reporting data following the current OMB standards for reporting by both race and ethnicity (table 4B). Accordingly, minority representation by race was highest for Blacks at 23.9% and lowest for Hawaiian/Pacific Islanders 0.2%. American Indian/Alaska Natives represented 3.6%, Asians 19.1%, and Whites 39.0% of participants (table 4B). Participants identifying as *More Than One Race* were 1.0% of the total number of participants (table 4B). In addition, 13.3% did not identify a race category (table 4B). Of the 486,563 participants enrolled in extramural and intramural Phase III research protocols in FY2009 and reported following the current OMB standards, 80.6 % of total participants identified as “Not Hispanic”, 10.7% identified as “Hispanic or Latino”, and 8.7% of the total participants did not identify an ethnicity category (table 4B). The racial distribution of the “Hispanic or Latino” participants is also provided separately (table 4B; New Form (Part B)).

In FY2009, 196 extramural and intramural Phase III research protocols reported data following the former OMB standards; minority representation was highest for Blacks (not Hispanic) at 9.0% and lowest for American Indian/Alaska Natives at 0.4% (table 4B). Asian/Pacific Islanders represented 2.0%, Hispanics were approximately 3.9%, and Whites (not Hispanic) 82.1% of the participants (table 4C). The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards.

Correspondingly, in FY2010 there were 743 extramural and intramural Phase III clinical research protocols, of which 696 protocols reported human subject participation (table 5A). Of these, 77.6% were domestic protocols and 22.4% were foreign protocols (table 5A). Clinical trials not included in this analysis are those studies that have just begun and have not reported enrollment data or have not begun recruiting patients. A total of 769,885 participants were enrolled in extramural and intramural Phase III research protocols of which 51.0% were domestic participants and 49.0% were foreign participants (table 5B). Of the 769,885 participants, 53.0% were women, 43.0% were men and 4.0% did not provide sex identification (table 5B). Further, 58.1% of the total participants, and 23.5% of Domestic-only participants, in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity (table 5C).

Moreover, in FY2010, there were 634 extramural and intramural Phase III research protocols reporting data following the current OMB standards for reporting by both race and ethnicity (table 6B). Accordingly, minority representation by race was highest for Blacks at 36.8% and lowest for Hawaiian/Pacific Islanders at 0.1% (table 6B). American Indian/Alaska Natives represented 2.3%, Asians 16.4%, and Whites 33.2% of participants (table 6B). Participants identifying as *More Than One Race* were 1.2% of the total number of participants (table 6B). In addition, 10.0% did not identify a race category (table 6B). Of the 691,450 participants enrolled in extramural and intramural Phase III research protocols in FY2010 and reported following the current OMB standards, 84.2% of total participants identified as “Not Hispanic”, 8.8% identified as “Hispanic or Latino”, and 7.0% of the total participants

did not identify an ethnicity category (table 6B). The racial distribution of the “Hispanic or Latino” participants is also provided separately (table 6B; New Form (Part B)).

Sixty-two extramural and intramural Phase III research protocols reported in FY2009 following the former OMB standards; minority representation was highest for Blacks (not Hispanic) at 8.8% and lowest for American Indian/Alaska Natives at 0.4%. Asian/Pacific Islanders represented approximately 1.5%, Hispanics were 4.1%, and Whites (not Hispanic) 84.2% of the participants (table 6C). The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards.

The number of participants in Phase III extramural and intramural clinical research in FY2010, 769,885, remained within the ranges reported since FY1995. Similarly, the proportion of males and females, 53.0%F and 43.0%M in FY2010, is similar to previous years (table 7A).

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

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2009 and 2010

In FY2009, there were 14,725 extramural clinical research protocols, including Phase III and other clinical studies, of which 9,444 protocols reported human subject participation (table 8A). Of these, 91.4% were domestic protocols and 8.6% were foreign protocols (table 8A). Approximately 16.2 million participants were enrolled in extramural research protocols of which 95.3% of the total enrollment is domestic participants and 4.7% of the total enrollment is foreign participants (table 8B). Of the 16.2 million participants, 62.9% were women, 36.5% were men and 0.52% did not provide sex identification (table 9A). Further, 30.4% of the total participants were reported as minorities (table 9A).

Correspondingly, in FY2010, there were 15,201 extramural clinical research protocols, including Phase III and other clinical studies, of which 10,309 protocols reported human subject participation (table 10A). Of these, 92.4% were domestic protocols and 7.6% were foreign protocols (table 10A). Approximately 20.3 million participants were enrolled in extramural research protocols of which 93.7% of the total enrollment is domestic participants and 6.3% of the total enrollment is foreign participants (table 10B). Of the 20.3 million participants, 58.1% were women, 41.2% were men and 0.74% did not provide sex identification (table 11A). Further, 32.5% of the total extramural participants were reported as minorities (table 11A).

While the number of participants in extramural clinical research protocols increased (16.2 million in FY2009 and 20.3 million in FY2010), the proportions of women and men shifted slightly (62.9%F and 36.5%M in FY2009 and 58.1%F and 41.2%M in FY2010). When sex-specific studies were excluded, the proportions of women and men in extramural clinical research reported in FY2009 were 50.2% for females and 49.0% for males (table 12A), and in FY2010 51.7% for females and 47.3% for males (table 13A).

NIH Defined Phase III Extramural Clinical Research: FY2009 and FY2010

In FY2009 there were 619 extramural Phase III clinical research protocols, of which 592 protocols reported human subject participation (table 14A). A total of 635,825 participants were enrolled in extramural Phase III research protocols of which 52.6% were women, 42.6% were men and 4.8% did not provide sex identification (table 15A).

In FY2009 there were 407 extramural Phase III research protocols reporting data following the current OMB standards for reporting race and ethnicity (table 15B). Minority representation by race was highest

for Blacks at 24.4% and lowest for Hawaiian/Pacific Islanders 0.18% (table 13B). American Indian/Alaska Natives represented 3.7%, Asians 19.6%, and Whites 39.9% of participants (table 15B). Participants identifying as *More Than One Race* were 0.99% of the total number of participants (table 15B). In addition, 11.3 % did not identify a race category (table 15B). Of the 473,128 participants enrolled in extramural and intramural Phase III research protocols in FY2009 and reported following the new OMB standards, 82.3 % of total participants identified as “Not Hispanic”, 9.4% of the total participants identified as “Hispanic or Latino”, and 8.3 % of the total participants did not identify an ethnicity category (table 15B). The racial distribution of the “Hispanic or Latino” participants is also provided separately (table 15B, New Form (Part B)).

In FY2010 there were 696 extramural Phase III clinical research protocols, of which 650 protocols reported human subject participation (table 16A). A total of 749,518 participants were enrolled in extramural Phase III research protocols of which 52.3% were women, 43.6% were men and 4.1% did not provide sex identification (table 17A).

Correspondingly in FY2010, there were 599 extramural Phase III research protocols reporting data following the current OMB standards for reporting race and ethnicity (table 17B). Minority representation by race was highest for Blacks at 37.4% and lowest for Hawaiian/Pacific Islanders 0.14%. American Indian/Alaska Natives represented 2.3%, Asians 16.7%, and Whites 33.5% of participants (table 17B). Participants identifying as *More Than One Race* were 1.2% of the total number of participants (table 17B). In addition, 8.7% did not identify a race category (table 17B). Of the 674,142 participants enrolled in extramural Phase III research protocols in FY2009 and reported following the new OMB standards, 85.4% of total participants identified as “Not Hispanic”, 7.8% of the total participants identified as “Hispanic or Latino”, and 6.8% of the total participants did not identify an ethnicity category (table 17B). The racial distribution of the “Hispanic or Latino” participants is also provided separately (table 17B, New Form (Part B)).

The number of extramural Phase III clinical research protocols and participants increased (619 protocol and 635,825 participants in FY2009 and 696 protocols and 749,815 participants in FY2010), but the proportion of women remained relatively stable (52.6%F and 42.6%M in FY2009 and 52.3%F and 43.6%M in FY2010) as did the proportion not providing sex identification (4.8% in FY2009 and 4.1% in FY2010). There was a sharp increase in the reported enrollment of Blacks or African Americans reported in FY2010 (254,738 participants) in comparison to FY2009 (116,233) resulting primarily from expanded enrollment in the NICHD Global Network for Women's and Children's Health Research, a large, foreign, Phase 3 Clinical Trial (U01HD040636).

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2009 and 2010

In FY2009 there were 1,964 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,727 protocols reported human subject participation (table 8A). Approximately 3.0 million participants were enrolled in intramural research protocols of which 42.4% were women, 56.1% were men and 1.5% did not provide sex identification (table 18A).

For the 1,335 intramural clinical research studies that reported data following the current OMB standards in FY2009, the largest racial minority group was Asians at 10.0 % and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.05% (table 18B). American Indian/Alaska Natives represented 0.75%, Blacks 9.8%, and Whites 63.5% of participants in all intramural clinical research (table 18B). Approximately 5.5% of participants reported *More Than One Race* as their racial category. In addition, 10.5 % did not identify a race category (table 18B). Of the 2,790,196 participants enrolled in intramural clinical research protocols in FY2009 and reported following the current OMB standards, 81.2% of total participants identified as “Not Hispanic”, 4.0% of the total participants identified as “Hispanic or Latino”,

and 14.8% of the total participants did not identify an ethnicity category (table 18B). The racial distribution of the “Hispanic or Latino” participants is also provided separately (table 18B).

Among the 392 intramural research protocols that report data following the former OMB standards, minority representation was highest for Blacks (not Hispanic) at 13.6% and lowest for American Indian/Alaska Natives at 0.17% (table 18C). Asian/Pacific Islanders represented 4.2%, Hispanics 5.6%, and Whites (not Hispanic) 74.9% of the intramural research study population (table 18C). The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards.

Correspondingly, in FY2010 there were 2,050 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,770 protocols reported human subject participation (table 10A). Approximately 3.1 million participants were enrolled in intramural research protocols of which 43.2% were women, 54.7% were men and 2.2% did not provide sex identification (table 19A).

For the 1,408 intramural clinical research studies that reported data following the current OMB standards in FY2010, the largest racial minority group was Black or African American, at 10.3%, and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.13% (table 19B). American Indian/Alaska Natives represented 0.79%, Asians 9.8%, and Whites 62.0% of participants in all intramural clinical research (table 19B). Approximately 5.4% of participants reported *More Than One Race* as their racial category (table 17). In addition, 11.6% did not identify a race category (table 19B). Of the 2,947,158 participants enrolled in intramural clinical research protocols in FY2010 and reported following the current OMB standards, 80.0% of total participants identified as “Not Hispanic”, 4.2% of the total participants identified as “Hispanic or Latino”, and 15.9% of the total participants did not identify an ethnicity category (table 19B). The racial distribution of the “Hispanic or Latino” participants is also provided separately (table 19B, New Form (Part B)).

Among the 362 intramural research protocols that report data following the former OMB standards, minority representation was highest for Blacks (not Hispanic) at 13.7% and lowest for American Indian/Alaska Natives at 0.19% (table 19C). Asian/Pacific Islanders represented 4.3%, Hispanics 5.3%, and Whites (not Hispanic) 74.9% of the intramural research study population (table 19C). The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards.

While the number of participants in intramural clinical research protocols increased slightly (3.0M in FY2009 and 3.1M in FY2010), there was no substantive change in the proportions of women and men (42.4%F and 56.1%M in FY2009 and 43.2%F and 54.7%M in FY2010).

NIH Defined Phase III Intramural Clinical Research: FY2009 and FY2010

In FY2009 there were 43 intramural Phase III clinical research protocols, of which 38 protocols reported human subject participation (table 14A). Of these, 89.5% of the total number of protocols are domestic and 10.5% of the total number of protocols is foreign (table 14A). A total of 16,475 participants were enrolled in intramural Phase III research protocols of which 36.4% are domestic participants and 63.6% are foreign participants (table 14B). Of the 16,475 participants, 68.7% were women, 31.2% were men and 0.08% did not provide sex identification (table 18A). Further, 56.1% of total participants in Phase III intramural clinical research protocols were reported as minorities (table 18A).

Correspondingly, in FY2010 there were 47 intramural Phase III clinical research protocols, of which 46 protocols reported human subject participation (table 16A). Of these, 91.3% of the total number of protocols is domestic and 8.7% of the total number of protocols is foreign (table 16A). A total of 20,367

participants were enrolled in intramural Phase III research protocols of which 48.4% of the total enrollment is domestic participants and 51.6% are foreign participants (table 16B). Of the 20,367 participants, 79.2% were women, 20.8% were men and 0.06% did not provide sex identification (table 21). Further, 55.0% of total participants in intramural Phase III clinical research protocols were reported as minorities following the OMB categories for race and ethnicity (table 21).

The number of participants enrolled in Phase III intramural clinical research protocols increased (16,475 in FY2009 and 20,367 in FY2010), as did the proportions of women (68.7%F and 31.2%M in FY2009 and 79.2%F and 20.8%M in FY2010).

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY1995 – FY2010

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 22B is a sixteen-year summary report showing a steady increase in the number of protocols and enrollment. Overall, the number of protocols with enrollment increased from 3,188 in FY1995 to 12,079 in FY2010 – a 3.8 fold increase (table 22A, Part I). Reported enrollment increased from approximately 1.0 million (FY1995) to 23.3 million (FY2010) – a 22.9 fold increase; minority enrollment increased from approximately 0.4 million (FY1995) to 7.5 million (FY2010) – a 20.1 fold increase in the number of minority participants in NIH clinical research (table 22A, Part I). The total number of protocols reported with enrollment data has increased such that, since FY2003 the number is in excess of 10,000 protocols per year.

With the deployment of an updated population tracking system in 2002 and the OMB requirement to report data using the current format, NIH was able to report domestic and foreign data in a better way. Thus, trend data are available for domestic and foreign protocols and participation beginning in FY2002. Domestic enrollment increased from 10.2 million (FY2002) to 21.5 million (FY2010) – a 2.1 fold increase (table 22A, Part II). Foreign enrollment increased from 0.9 million (FY2002) to 1.8 million (FY2010) – a 1.9 fold increase (table 22A, Part II). Overall, the total enrollment has increased with domestic participation ranging between 75.9 to 93.3% and foreign participation ranging between 6.1 to 24.1%. In FY2010, domestic and foreign enrollment was 92.1% and 7.9% respectively (table 22C).

Table 23 is a summary report of all extramural and intramural clinical research by sex/gender and minority representation following the old and new data formats for domestic and foreign studies. The report demonstrates that female participation in all extramural and intramural research generally ranged between 51.7% and 64.2%, male participation in all extramural and intramural research ranged between 34.0% and 45.0% (table 23A). Overall minority participation in all extramural and intramural clinical research ranged between 28.6% and 43.1% (table 23A).

Table 23E provides a comparison of domestic and foreign participation between FY2002 and FY2010. The vast majority of the total clinical research protocols are domestic (91.9% to 96.4%, table 21E). Although the number of foreign protocols has increased, they comprise only about 3.6% to 8.1% of the total clinical research protocols with enrollment. Table 23F shows domestic and foreign minority enrollment for the nine-year period (FY2002-FY2010). Minority enrollment varied between 24.1% and 28.9% of total domestic participation, while minority enrollment varied between 67.7% and 90.9% of total foreign participation (table 23F).

Table 7 is a summary of NIH-funded Phase III extramural and intramural clinical research by sex/gender and minority enrollment following the old and new data reporting formats for domestic and foreign studies. This table demonstrates that female participation in NIH funded Phase III extramural and intramural clinical research generally ranged between 53.0% and 74.8% and male participation in NIH-funded Phase III extramural and intramural clinical research ranged between 24.3% and 44.6% (table 4A). Overall minority participation in NIH-funded Phase III extramural and intramural clinical research ranged from 22.5% to 41.4% (table 7A). Table 7E provides a comparison of domestic and foreign participation between FY2002 and FY2010. The majority of protocols are domestic, ranging from 72.5% and 95.8% of the total Phase III clinical research protocols. The number of foreign protocols has ranged from 4.2% to 27.5% during this time. Table 7F shows domestic and foreign enrollment for the same nine-year period. Minority enrollment varied between 20.2% and 25.4% of total domestic participation,

while minority enrollment in NIH-funded Phase III clinical research varied between 48.4% and 96.2% of total foreign participation.

**Aggregate Enrollment Data Tables
For Extramural and Intramural
Research Protocols**

***Fiscal Year 2010 Summary Reports
Fourteen-year Trend Summary Reports***

Table 1. Summary of NIH Clinical Research Reported In FY2009: Total Number of Protocols and Enrollment by Sex and Domestic versus Foreign Protocols

Table 1A. PROTOCOLS REPORTED	Total All Clinical Studies*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Protocols with Enrollment	11,171	10,263	91.9%	908	8.1%
% Protocols with Enrollment	66.9%	65.9%		81.3%	
Protocols with zero enrollment (Enrollment data have not yet been submitted)	5,518	5,309	96.2%	209	3.8%
% Protocols with zero enrollment	33.1%	34.1%		18.7%	
Total Number of Protocols	16,689	15,572	93.3%	1,117	6.7%
Total %	100.0%	100.0%		100.0%	

Table 1B. ENROLLMENT REPORTED	Total All Clinical Studies*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Females Enrolled	11,439,143	10,694,225	93.5%	744,918	6.5%
% Females Enrolled	59.8%	59.9%		57.7%	
Males Enrolled	7,570,646	7,033,607	92.9%	537,039	7.1%
% Males Enrolled	39.6%	39.4%		41.6%	
Sex of Subjects is Unknown	128,949	120,242	93.2%	8,707	6.8%
% Unknown Sex	0.7%	0.7%		0.7%	
Total Subjects Enrolled	19,138,738	17,848,074	93.3%	1,290,664	6.7%
Total %	100.0%	100.0%		100.0%	

Table 1C. MINORITY ENROLLMENT REPORTED	Total All Clinical Studies*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Minority Total**	5,783,543	4,883,794	84.4%	899,749	15.6%
% Minority Enrollment	30.2%	27.4%		69.7%	

* 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 Page 4 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%.

Table 2. Summary of NIH Clinical Research Reported In FY2010: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

Table 2A. PROTOCOLS REPORTED	Total All Clinical Studies*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Protocols with Enrollment	12,079	11,189	92.6%	890	7.4%
% Protocols with Enrollment	70.0%	69.7%		74.2%	
Protocols with zero enrollment. (Enrollment data have not yet been submitted)	5,172	4,862	94.0%	310	6.0%
% Protocols with zero Enrollment	30.0%	30.3%		25.8%	
Total Number of Protocols	17,251	16,051	93.0%	1,200	7.0%
Total %	100.0%	100.0%		100.0%	

Table 2B. ENROLLMENT REPORTED	Total All Clinical Studies*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Females Enrolled	13,102,832	12,018,942	91.7%	1,083,890	8.3%
% Females Enrolled	56.1%	55.8%		58.9%	
Males Enrolled	10,044,444	9,301,128	92.6%	743,316	7.4%
% Males Enrolled	43.0%	43.2%		40.4%	
Sex of Subjects is Unknown	216,359	203,006	93.8%	13,353	6.2%
% Unknown Sex	0.9%	0.9%		0.7%	
Total Subjects Enrolled	23,363,635	21,523,076	92.1%	1,840,559	7.9%
Total %	100.0%	100.0%		100.0%	

Table 2C. MINORITY ENROLLMENT REPORTED	Total All Clinical Studies*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Minority Total**	7,510,763	6,041,531	80.4%	1,469,232	19.6%
% Minority Enrollment	32.1%	28.1%		79.8%	

* 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 Page 4 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%.

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2009: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

Table 3A. PROTOCOLS REPORTED	Total of Phase III Clinical Trials*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Protocols with Enrollment	630	451	71.6%	179	28.4%
% Protocols with Enrollment	95.2%	94.2%		97.8%	
Protocols with zero enrollment (Enrollment data have not yet been submitted)	32	28	87.5%	4	12.5%
% Protocols with zero enrollment	4.8%	5.8%		2.2%	
Total Number of Protocols	662	479	72.4%	183	27.6%
Total %	100.0%	100.0%		100.0%	

Table 3B. ENROLLMENT REPORTED	Total of Phase III Clinical Trials*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Females Enrolled	345,748	232,936	67.4%	112,812	32.6%
% Females Enrolled	53.0%	53.7%		51.7%	
Males Enrolled	276,159	171,078	61.9%	105,081	38.1%
% Males Enrolled	42.3%	39.4%		48.1%	
Sex of Subjects is Unknown	30,393	29,881	98.3%	512	0.0%
% Unknown Sex	4.7%	6.9%		0.2%	
Total Subjects Enrolled	652,300	433,895	66.5%	218,405	33.5%
Total %	100.0%	100.0%		100.0%	

Table 3C. MINORITY ENROLLMENT REPORTED**	Total of Phase III Clinical Trials*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Minority Total for all Phase III studies	291,949	97,079	33.3%	194,870	66.7%
% Minority Enrollment	44.8%	22.4%		89.2%	

* 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 Page 4 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%.

**Table 4. Aggregate Enrollment Data for Extramural and Intramural Phase III Research
Funded in FY2008 and Reported in FY2009: Percent Analysis**

Table 4A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	345,748	157,952	45.68%
Females (% of total)	53.00%	54.10%	
Males (#)	276,159	133,282	48.26%
Males (% of total)	42.34%	45.65%	
Unknown (#)	30,393	715	2.35%
Unknown (% of total)	4.66%	0.24%	
TOTAL (#)	652,300	291,949	44.76%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 630
--

Table 4B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	9,875	47,848	61,823	438	107,105	2,283	23,530	252,902
% of total	2.03%	9.83%	12.71%	0.09%	22.01%	0.47%	4.84%	51.98%
<i>% females in each race</i>	3.90%	18.92%	24.45%	0.17%	42.35%	0.90%	9.30%	100.00%
<i>% of each race females</i>	56.40%	51.52%	53.19%	50.99%	56.51%	48.82%	36.26%	51.98%
Males (number)	7,575	44,912	54,229	417	81,253	2,334	12,585	203,305
% of total	1.56%	9.23%	11.15%	0.09%	16.70%	0.48%	2.59%	41.78%
<i>% males in each race</i>	3.73%	22.09%	26.67%	0.21%	39.97%	1.15%	6.19%	100.00%
<i>% of each race males</i>	43.26%	48.36%	46.66%	48.54%	42.87%	49.91%	19.39%	41.78%
Unknown (number)	59	108	181	4	1,169	59	28,776	30,356
% of total	0.01%	0.02%	0.04%	0.00%	0.24%	0.01%	5.91%	6.24%
<i>% unknown in each race</i>	0.19%	0.36%	0.60%	0.01%	3.85%	0.19%	94.80%	100.00%
<i>% of each race unknown</i>	0.34%	0.12%	0.16%	0.47%	0.62%	1.26%	44.35%	6.24%
Total (number)	17,509	92,868	116,233	859	189,527	4,676	64,891	486,563
% of each race in total	3.60%	19.09%	23.89%	0.18%	38.95%	0.96%	13.34%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown / Not Reported	Total
Females (number)	210,945	34,357	7,600	252,902
% of total	43.35%	7.06%	1.56%	51.98%
<i>% females in each ethnicity</i>	83.41%	13.59%	3.01%	100.00%
<i>% of each ethnicity females</i>	53.81%	65.79%	17.95%	51.98%
Males (number)	179,583	17,487	6,235	203,305
% of total	36.91%	3.59%	1.28%	41.78%
<i>% males in each ethnicity</i>	88.33%	8.60%	3.07%	100.00%
<i>% of each ethnicity males</i>	45.81%	33.49%	14.72%	41.78%
Unknown (number)	1,462	379	28,515	30,356
% of total	0.30%	0.08%	5.86%	6.24%
<i>% unknown in each ethnicity</i>	4.82%	1.25%	93.94%	100.00%
<i>% of each ethnicity unknown</i>	0.37%	0.73%	67.33%	6.24%
Total (number)	391,990	52,223	42,350	486,563
% of each ethnicity in total	80.56%	10.73%	8.70%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 434

III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race

Sex/ Gender	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
Females (number)	8,729	138	488	99	7,265	431	17,207	34,357	146,739
% of total	16.71%	0.26%	0.93%	0.19%	13.91%	0.83%	32.95%	65.79%	30.16%
<i>% females in each race</i>	25.41%	0.40%	1.42%	0.29%	21.15%	1.25%	50.08%	100.00%	58.02%
<i>% of each race females</i>	57.00%	39.32%	52.08%	50.00%	63.25%	44.71%	74.90%	65.79%	55.04%
Males (number)	6,543	203	439	95	4,160	521	5,526	17,487	119,153
% of total	12.53%	0.39%	0.84%	0.18%	7.97%	1.00%	10.58%	33.49%	24.49%
<i>% males in each race</i>	37.42%	1.16%	2.51%	0.54%	23.79%	2.98%	31.60%	100.00%	58.61%
<i>% of each race males</i>	42.73%	57.83%	46.85%	47.98%	36.21%	54.05%	24.05%	33.49%	44.69%
Unknown (number)	41	10	10	4	62	12	240	379	713
% of total	0.08%	0.02%	0.02%	0.01%	0.12%	0.02%	0.46%	0.73%	0.15%
<i>% unknown in each race</i>	10.82%	2.64%	2.64%	1.06%	16.36%	3.17%	63.32%	100.00%	2.35%
<i>% of each race unknown</i>	0.27%	2.85%	1.07%	2.02%	0.54%	1.24%	1.04%	0.73%	0.27%
Total (number)	15,313	351	937	198	11,487	964	22,973	52,223	266,605
% of each race in total	29.32%	0.67%	1.79%	0.38%	22.00%	1.85%	43.99%	100.00%	54.79%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 4C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 196
Females (number)	352	2,114	6,122	2,625	79,752	1,881	92,846	11,213	
% of total	0.21%	1.28%	3.69%	1.58%	48.12%	1.13%	56.02%	6.77%	
<i>% females in each race</i>	0.38%	2.28%	6.59%	2.83%	85.90%	2.03%	100.00%	12.08%	
<i>% of each race females</i>	57.42%	64.24%	40.93%	40.48%	58.61%	43.63%	56.02%	44.24%	
Males (number)	261	1,176	8,833	3,859	56,319	2,406	72,854	14,129	
% of total	0.16%	0.71%	5.33%	2.33%	33.98%	1.45%	43.96%	8.52%	
<i>% males in each race</i>	0.36%	1.61%	12.12%	5.30%	77.30%	3.30%	100.00%	19.39%	
<i>% of each race males</i>	42.58%	35.73%	59.06%	59.52%	41.39%	55.81%	43.96%	55.75%	
Unknown (number)	0	1	1	0	11	24	37	2	
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.02%	0.00%	
<i>% unknown in each race</i>	0.00%	2.70%	2.70%	0.00%	29.73%	64.86%	100.00%	5.41%	
<i>% of each race unknown</i>	0.00%	0.03%	0.01%	0.00%	0.01%	0.56%	0.02%	0.01%	
Total (number)	613	3,291	14,956	6,484	136,082	4,311	165,737	25,344	
% of each race in total	0.37%	1.99%	9.02%	3.91%	82.11%	2.60%	100.00%	15.29%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 4A.

Table 5. Summary of NIH Phase III Clinical Research Reported In FY2010: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

Table 5A. PROTOCOLS REPORTED	Total of Phase III Clinical Trials*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Protocols with Enrollment	696	540	77.6%	156	22.4%
% Protocols with Enrollment	93.7%	93.1%		95.7%	
Protocols with zero enrollment (Enrollment data have not yet been submitted)	47	40	85.1%	7	14.9%
% Protocols with zero enrollment	6.3%	6.9%		4.3%	
Total Number of Protocols	743	580	78.1%	163	21.9%
Total %	100.0%	100.0%		100.0%	

Table 5B. ENROLLMENT REPORTED	Total of Phase III Clinical Trials*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Females Enrolled	408,181	197,608	48.4%	210,573	51.6%
% Females Enrolled	53.0%	50.3%		55.9%	
Males Enrolled	330,808	165,205	49.9%	165,603	50.1%
% Males Enrolled	43.0%	42.1%		43.9%	
Sex of Subjects is Unknown	30,896	30,054	97.3%	842	0.0%
% Unknown Sex	4.0%	7.6%		0.2%	
Total Subjects Enrolled	769,885	392,867	51.0%	377,018	49.0%
Total %	100.0%	100.0%		100.0%	

Table 5C. MINORITY ENROLLMENT REPORTED**	Total of Phase III Clinical Trials*	Domestic Protocols	% Domestic Protocols	Foreign Protocols	% Foreign Protocols
Minority Total for all Phase III studies	447,187	92,509	20.7%	354,678	79.3%
% Minority Enrollment	58.1%	23.5%		94.1%	

* 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 Page 4 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%.

Table 6. Aggregate Enrollment Data for Extramural and Intramural Phase III Research Funded in FY2009 and Reported in FY2010: Percent Analysis

Table 6A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	408,181	250,716	61.42%
Females (% of total)	53.02%	56.07%	
Males (#)	330,808	195,249	59.02%
Males (% of total)	42.97%	43.66%	
Unknown (#)	30,896	1,222	3.96%
Unknown (% of total)	4.01%	0.27%	
TOTAL (#)	769,885	447,187	58.08%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 696
--

Table 6B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards
I. Total of All Subjects by Race

Sex/Gender	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	7,972	62,284	143,931	482	129,143	3,125	27,173	374,110
% of total	1.15%	9.01%	20.82%	0.07%	18.68%	0.45%	3.93%	54.11%
<i>% females in each race</i>	2.13%	16.65%	38.47%	0.13%	34.52%	0.84%	7.26%	100.00%
<i>% of each race females</i>	50.31%	55.10%	56.50%	51.50%	56.29%	37.84%	39.26%	54.11%
Males (number)	7,817	50,663	110,032	450	99,645	5,073	12,768	286,448
% of total	1.13%	7.33%	15.91%	0.07%	14.41%	0.73%	1.85%	41.43%
<i>% males in each race</i>	2.73%	17.69%	38.41%	0.16%	34.79%	1.77%	4.46%	100.00%
<i>% of each race males</i>	49.33%	44.82%	43.19%	48.08%	43.44%	61.43%	18.45%	41.43%
Unknown (number)	57	95	775	4	622	60	29,279	30,892
% of total	0.01%	0.01%	0.11%	0.00%	0.09%	0.01%	4.23%	4.47%
<i>% unknown in each race</i>	0.18%	0.31%	2.51%	0.01%	2.01%	0.19%	94.78%	100.00%
<i>% of each race unknown</i>	0.36%	0.08%	0.30%	0.43%	0.27%	0.73%	42.30%	4.47%
Total (number)	15,846	113,042	254,738	936	229,410	8,258	69,220	691,450
% of each race in total	2.29%	16.35%	36.84%	0.14%	33.18%	1.19%	10.01%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	325,083	38,153	10,874	374,110
% of total	47.01%	5.52%	1.57%	54.11%
<i>% females in each ethnicity</i>	86.90%	10.20%	2.91%	100.00%
<i>% of each ethnicity females</i>	55.83%	62.94%	22.39%	54.11%
Males (number)	255,655	22,154	8,639	286,448
% of total	36.97%	3.20%	1.25%	41.43%
<i>% males in each ethnicity</i>	89.25%	7.73%	3.02%	100.00%
<i>% of each ethnicity males</i>	43.91%	36.55%	17.79%	41.43%
Unknown (number)	1,529	311	29,052	30,892
% of total	0.22%	0.04%	4.20%	4.47%
<i>% unknown in each ethnicity</i>	4.95%	1.01%	94.04%	100.00%
<i>% of each ethnicity unknown</i>	0.26%	0.51%	59.82%	4.47%
Total (number)	582,267	60,618	48,565	691,450
% of each ethnicity in total	84.21%	8.77%	7.02%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 634

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	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
Females (number)	6,517	144	565	104	9,687	642	20,494	38,153	247,975
% of total	10.75%	0.24%	0.93%	0.17%	15.98%	1.06%	33.81%	62.94%	35.86%
<i>% females in each race</i>	17.08%	0.38%	1.48%	0.27%	25.39%	1.68%	53.72%	100.00%	66.28%
% of each race females	49.71%	40.00%	52.51%	50.98%	62.99%	20.70%	74.83%	62.94%	56.93%
Males (number)	6,553	206	501	96	5,645	2,444	6,709	22,154	186,389
% of total	10.81%	0.34%	0.83%	0.16%	9.31%	4.03%	11.07%	36.55%	26.96%
<i>% males in each race</i>	29.58%	0.93%	2.26%	0.43%	25.48%	11.03%	30.28%	100.00%	65.07%
% of each race males	49.98%	57.22%	46.56%	47.06%	36.71%	78.81%	24.50%	36.55%	42.79%
Unknown (number)	41	10	10	4	46	15	185	311	1,222
% of total	0.07%	0.02%	0.02%	0.01%	0.08%	0.02%	0.31%	0.51%	0.18%
<i>% unknown in each race</i>	13.18%	3.22%	3.22%	1.29%	14.79%	4.82%	59.49%	100.00%	3.96%
% of each race unknown	0.31%	2.78%	0.93%	1.96%	0.30%	0.48%	0.68%	0.51%	0.28%
Total (number)	13,111	360	1,076	204	15,378	3,101	27,388	60,618	435,586
% of each race in total	21.63%	0.59%	1.78%	0.34%	25.37%	5.12%	45.18%	100.00%	63.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 6C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 62
Females (number)	142	565	1,304	730	30,962	368	34,071	2,741	
% of total	0.18%	0.72%	1.66%	0.93%	39.47%	0.47%	43.44%	3.49%	
<i>% females in each race</i>	0.42%	1.66%	3.83%	2.14%	90.87%	1.08%	100.00%	8.04%	
% of each race females	47.97%	47.40%	18.93%	22.64%	46.85%	49.13%	43.44%	23.63%	
Males (number)	154	627	5,584	2,495	35,120	380	44,360	8,860	
% of total	0.20%	0.80%	7.12%	3.18%	44.78%	0.48%	56.56%	11.30%	
<i>% males in each race</i>	0.35%	1.41%	12.59%	5.62%	79.17%	0.86%	100.00%	19.97%	
% of each race males	52.03%	52.60%	81.07%	77.36%	53.14%	50.73%	56.56%	76.37%	
Unknown (number)	0	0	0	0	3	1	4	0	
% of total	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	
<i>% unknown in each race</i>	0.00%	0.00%	0.00%	0.00%	75.00%	25.00%	100.00%	0.00%	
% of each race unknown	0.00%	0.00%	0.00%	0.00%	0.00%	0.13%	0.01%	0.00%	
Total (number)	296	1,192	6,888	3,225	66,085	749	78,435	11,601	
% of each race in total	0.38%	1.52%	8.78%	4.11%	84.25%	0.95%	100.00%	14.79%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 6a.

Table 7. Sixteen-Year Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2010

Table 7A. Phase III SIXTEEN YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER AND MINORITIES IN ALL PHASE 3 PROTOCOLS (Old + New Forms)

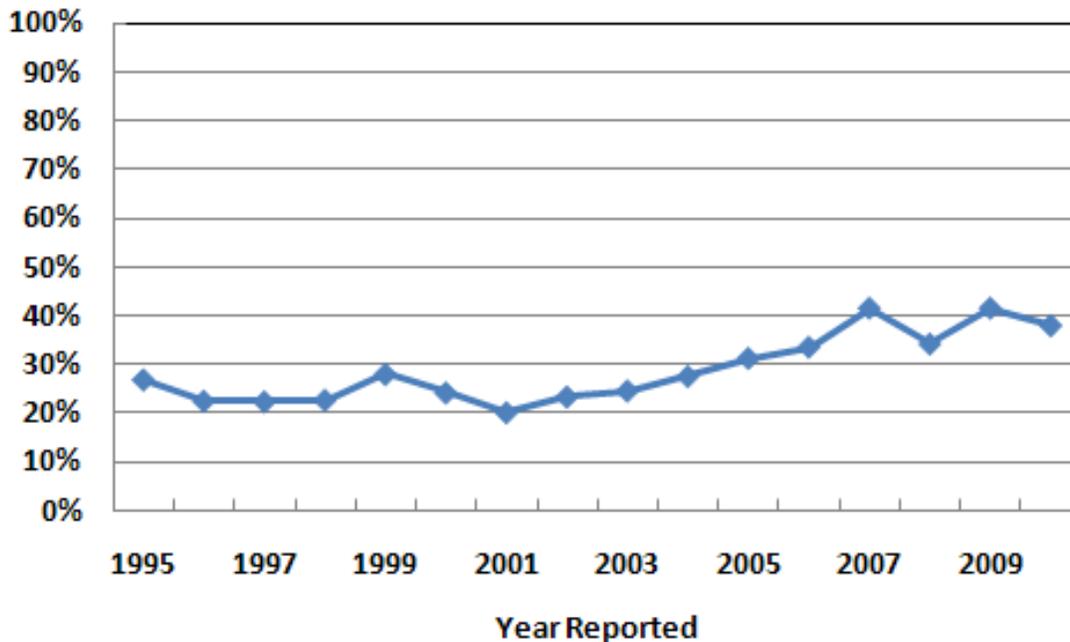
FY Reported/ Funded	Form	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms)
1995/1994	Old	171,181	108,324	19,818	299,323	80,562	560
% Reported in 1995		57.2%	36.2%	6.6%	100.0%	26.9%	
1996/1995	Old	264,755	203,698	21,210	489,663	110,669	608
% Reported in 1996		54.1%	41.6%	4.3%	100.0%	22.6%	
1997/1996	Old	264,755	203,698	21,210	489,663	110,000	608
% Reported in 1997		54.1%	41.6%	4.3%	100.0%	22.5%	
1998/1997	Old	228,417	74,389	2,705	305,511	69,599	320
% Reported in 1998		74.8%	24.3%	0.9%	100.0%	22.8%	
1999/1998	Old	339,533	163,950	1,446	504,929	141,449	578
% Reported in 1999		67.2%	32.5%	0.3%	100.0%	28.0%	
2000/1999	Old	313,952	180,705	1,086	495,743	120,339	589
% Reported in 2000		63.3%	36.5%	0.2%	100.0%	24.3%	
2001/2000	Old	412,379	168,085	1,273	581,737	117,873	645
% Reported in 2001		70.9%	28.9%	0.2%	100.0%	20.3%	
2002/2001	Old + New	278,876	195,090	781	474,747	111,269	754
% Reported in 2002		58.7%	41.1%	0.2%	100.0%	23.4%	
2003/2002	Old + New	294,950	239,403	1,914	536,267	132,302	852
% Reported in 2003		55.0%	44.6%	0.4%	100.0%	24.7%	
2004/2003	Old + New	301,353	242,913	1,101	545,367	150,456	573
% Reported in 2004		55.3%	44.5%	0.2%	100.0%	27.6%	
2005/2004	Old + New	290,977	197,300	4,723	493,000	154,191	547
% Reported in 2005		59.0%	40.0%	1.0%	100.0%	31.3%	
2006/2005	Old + New	314,066	179,975	5,389	499,430	167,446	624
% Reported in 2006		62.9%	36.0%	1.1%	100.0%	33.5%	
2007/2006	Old + New	324,694	249,633	16,832	591,159	244,932	621
% Reported in 2007		54.9%	42.2%	2.8%	100.0%	41.4%	
2008/2007	Old + New	455,612	319,732	17,234	792,578	270,899	639
% Reported in 2008		57.5%	40.3%	2.2%	100.0%	34.2%	
2009/2008	Old + New	345,748	276,159	30,393	652,300	291,949	630
% Reported in 2009		53.0%	42.3%	4.7%	100.0%	41.4%	
2010/2009	Old + New	408,181	330,808	30,896	769,885	447,187	696
% Reported in 2010		53.0%	43.0%	4.0%	100.0%	37.9%	

Table 7A Comments:

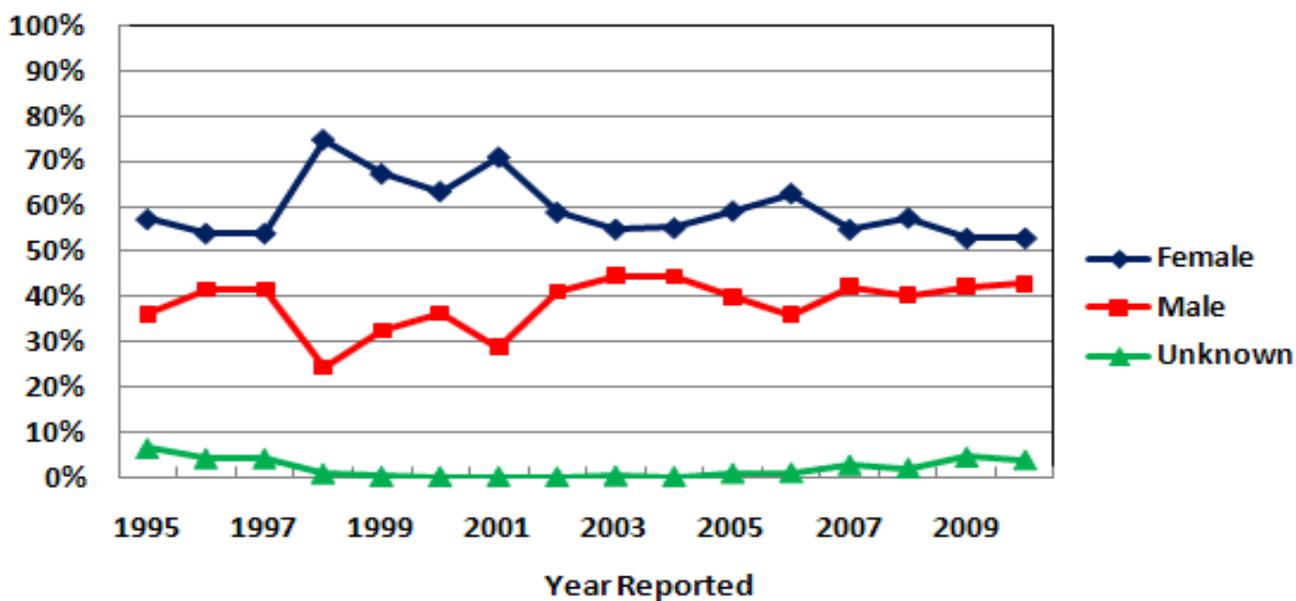
1. Table 7A summarizes enrollment by sex/gender and minority race/ethnicity categories for the sixteen year reporting period (1995-2010). The data are compiled from Tables 7B, 7C and 7D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 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).

Figure 7a. Sixteen-Year Trend Summary of Enrollment in NIH Extramural and Intramural Phase III Clinical Research

Minority Phase III Enrollment by Year Reported



Male and Female Phase III Enrollment by Year Reported



Note: Trend data vary over time because the data for each year represent the net total resulting from (1) studies continuing from the prior year; (2) the addition of new studies reported; and (3) subtraction of studies that are not longer reported.

Table 7 (cont'd): Sixteen-Year Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2010

Notes: Tables 7B-D

NOTE 1: The shaded portions of the Tables 7B, 7C and 7D 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.

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

FY Reported/ 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
% Reported in 1995	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
% Reported in 1996	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
% Reported in 1997	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
% Reported in 1998	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
% Reported in 1999	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
% Reported in 2000	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
% Reported in 2001	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
% Reported in 2002	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
% Reported in 2003	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
% Reported in 2004	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
% Reported in 2005	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
% Reported in 2006	0.4%	7.3%	8.9%	4.1%	76.5%	2.8%	100.0%	20.8%	
2007/2006	751	3,943	21,582	9,333	169,789	4,259	209,657	35,609	197
% Reported in 2007	0.4%	1.9%	10.3%	4.5%	81.0%	2.0%	100.0%	17.0%	
2008/2007	900	4,542	22,445	6,642	190,753	4,262	232,544	37,529	164
% Reported in 2008	0.4%	2.0%	9.7%	4.1%	82.0%	1.8%	100.0%	16.1%	
2009/2008	613	3,291	14,956	6,484	136,082	4,311	165,737	25,344	196
% Reported in 2009	0.4%	2.0%	9.0%	3.9%	82.1%	2.6%	100.0%	15.3%	
2010/2009	296	1,192	6,888	3,225	66,085	749	78,435	11,601	62
% Reported in 2010	0.4%	1.5%	8.8%	4.1%	84.3%	1.0%	100.0%	14.8%	

Table 7 (cont'd): Nine-Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2010: Enrollment by Race and Ethnicity

1. The New Form consists of Parts A and B (Tables 7C and 7D) for reporting years 2002-2009. 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.

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

I. Total of All Subjects by Race

FY Reported/Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total*
2002/2001	159	799	4,647	52	34,654	560	2,273	43,144
% Reported in 2002	0.37%	1.85%	10.77%	0.12%	80.32%	1.30%	5.27%	100.00%
2003/2002	484	2,609	21,641	220	47,869	989	8,138	81,950
% Reported in 2003	0.6%	3.2%	26.4%	0.3%	58.4%	1.2%	9.9%	100.0%
2004/2003	1,396	4,385	43,721	611	106,793	4,419	5,657	166,982
% Reported in 2004	0.8%	2.6%	26.2%	0.4%	64.0%	2.6%	3.4%	100.0%
2005/2004	2,164	9,192	50,338	462	101,238	3,063	10,254	176,711
% Reported in 2005	1.2%	5.2%	28.5%	0.3%	57.3%	1.7%	5.8%	100.0%
2006/2005	4,630	32,360	50,780	535	126,670	4,246	50,446	269,667
% Reported in 2006	1.7%	12.0%	18.8%	0.2%	47.0%	1.6%	18.7%	100.0%
2007/2006	9,351	47,364	84,468	555	133,002	4,145	102,617	381,502
% Reported in 2007	2.5%	12.4%	22.1%	0.1%	34.9%	1.1%	26.9%	100.0%
2008/2007	15,006	95,296	103,166	716	281,344	12,136	52,370	560,034
% Reported in 2008	2.7%	17.0%	18.4%	0.1%	50.2%	2.2%	9.4%	100.0%
2009/2008	17,509	92,868	116,233	859	189,527	4,676	64,891	486,563
% Reported in 2009	3.6%	19.1%	23.9%	0.2%	39.0%	1.0%	13.3%	100.0%
2010/2009	15,846	113,042	254,738	936	229,410	8,258	69,220	691,450
% Reported in 2010	2.3%	16.3%	36.8%	0.1%	33.2%	1.2%	10.0%	100.0%

II. Total of All Subjects by Ethnicity

FY Reported/Funded	Not Hispanic	Hispanic or Latino**	Unknown/ Not Reported	Total*
2002/2001	36,224	1,630	5,290	43,144
% Reported in 2002	83.96%	3.78%	12.26%	100.00%
2003/2002	64,295	7,831	9,824	81,950
% Reported in 2003	78.5%	9.6%	12.0%	100.0%
2004/2003	145,742	13,435	7,805	166,982
% Reported in 2004	87.3%	8.0%	4.7%	100.0%
2005/2004	156,650	10,397	9,664	176,711
% Reported in 2005	88.6%	5.9%	5.5%	100.0%
2006/2005	202,358	31,034	36,275	269,667
% Reported in 2006	75.0%	11.5%	13.5%	100.0%
2007/2006	254,692	71,622	55,188	381,502
% Reported in 2007	66.8%	18.8%	14.5%	100.0%
2008/2007	460,862	64,351	34,821	560,034
% Reported in 2008	82.3%	11.5%	6.2%	100.0%
2009/2008	391,990	52,223	42,350	486,563
% Reported in 2009	80.6%	10.7%	8.7%	100.0%
2010/2009	582,267	60,618	48,565	691,450
% Reported in 2010	84.2%	8.8%	7.0%	100.0%

* These totals must agree

** The Hispanic enrollment totals must agree with totals in Table 7D.

Table 7C Comment: In FY2009, the NICHD Global Network for Women's and Children's Health Research, a large, foreign, Phase 3 Clinical Trial (U01HD040636) expanded enrollment, causing a sharp increase in the reported enrollment of Blacks or African Americans reported in FY2010.

Table 7 (cont'd): Nine-Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2010: Enrollment by Race and Ethnicity

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

FY Reported/Funded	American Indian/Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total**	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Protocols with Enrollment data (New Form):
2002/2001	49	22	31	4	660	304	560	1,630	7,437	94
% Reported in 2002	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
% Reported in 2003	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
% Reported in 2004	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
% Reported in 2005	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
% Reported in 2006	7.4%	0.2%	2.3%	0.1%	22.1%	2.3%	65.5%	100.0%	44.4%	
2007/2006	7,333	45	458	24	7,430	322	56,010	71,622	209,323	424
% Reported in 2007	10.2%	0.1%	0.6%	0.0%	10.4%	0.4%	78.2%	100.0%	54.9%	
2008/2007	13,060	229	717	122	22,293	5,654	22,276	64,351	270,889	475
% Reported in 2008	7.3%	0.4%	4.3%	0.4%	35.3%	4.1%	48.2%	100.0%	48.4%	
2009/2008	15,313	351	937	198	11,487	964	22,973	52,223	266,605	434
% Reported in 2009	29.3%	0.7%	1.8%	0.4%	22.0%	1.8%	44.0%	100.0%	54.8%	
2010/2009	13,111	360	1,076	204	15,378	3,101	27,388	60,618	435,586	634
% Reported in 2010	21.6%	0.6%	1.8%	0.3%	25.4%	5.1%	45.2%	100.0%	0.0%	

** These totals must agree with the Hispanic enrollment in Table 7C.II

Table 7 (cont'd): Nine-Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2010: Enrollment by Race and Ethnicity

Table 7E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2010

FY Reported/ 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	474,747	444,436	93.6%	30,311	6.4%	754	582	77.2%	172	22.8%
2003/2002	536,267	486,857	90.8%	49,410	9.2%	852	643	75.5%	209	24.5%
2004/2003	545,367	496,241	91.0%	49,126	9.0%	573	549	95.8%	24	4.2%
2005/2004	493,000	437,902	88.8%	55,098	11.2%	547	517	94.5%	30	5.5%
2006/2005	499,430	400,297	80.2%	99,133	19.8%	624	564	90.4%	60	9.6%
2007/2006	591,159	428,440	72.5%	162,719	27.5%	653	609	93.3%	44	6.7%
2008/2007	792,578	591,105	74.6%	201,473	25.4%	639	585	91.5%	54	8.5%
2009/2008	652,300	433,895	66.5%	218,405	33.5%	630	451	71.6%	179	28.4%
2010/2009	769,885	392,867	51.0%	377,018	49.0%	696	540	77.6%	156	22.4%

Table 7E comments:

1. The Total Enrollment, Total Domestic and Total Foreign Enrollment increased overall from FY 2002 – 2010.
2. The Percent Domestic enrollment decreased from over 90% reported in FY2002 to less than 80% reported in FY2010. Percent Foreign enrollment has correspondingly increased during the same period.

Figure 7b. Nine-Year Trend Summary of Domestic and Foreign Enrollment in NIH Extramural and Intramural Phase III Clinical Research

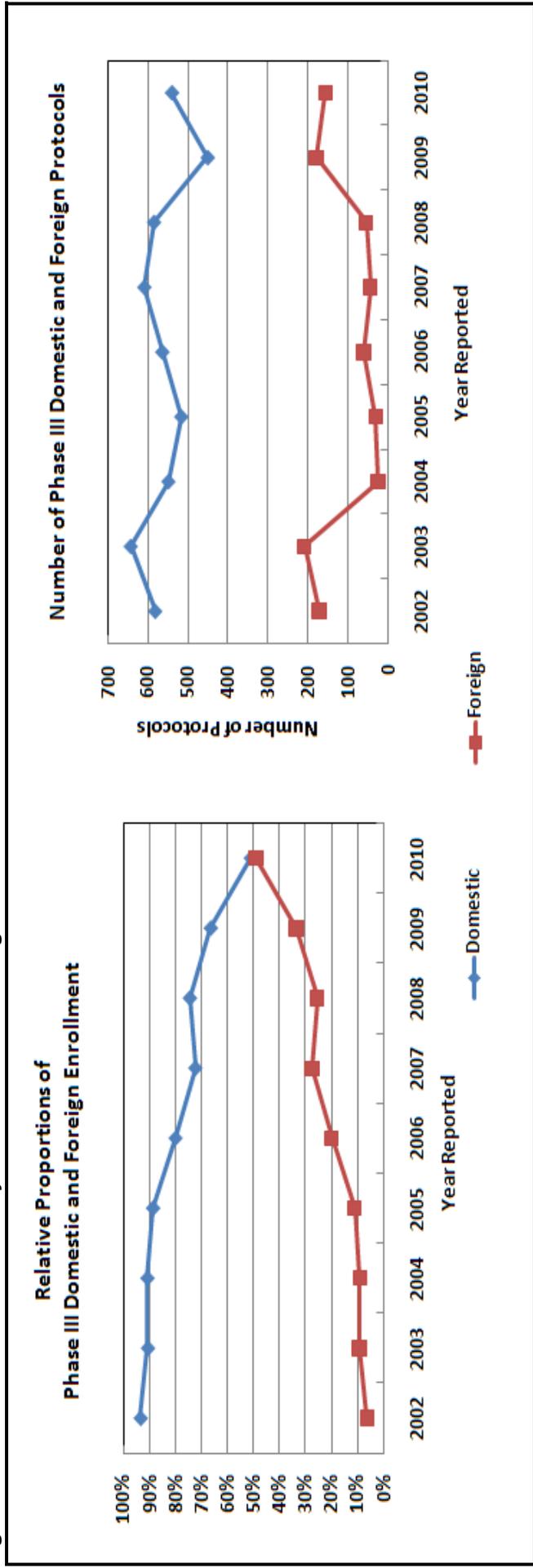


Table 7 (cont'd): Nine-Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2010: Enrollment by Race and Ethnicity

Table 7F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2010

FY Reported/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
% Reported in 2002	60.4%	100.0%	20.9%	100.0%
2003/2002	23,927	49,410	109,376	486,857
% Reported in 2003	48.4%	100.0%	22.5%	100.0%
2004/2003	37,126	49,126	125,813	496,241
% Reported in 2004	75.6%	100.0%	25.4%	100.0%
2005/2004	44,281	55,098	109,910	437,902
% Reported in 2005	80.4%	100.0%	25.1%	100.0%
2006/2005	84,412	99,133	83,034	400,297
% Reported in 2006	85.2%	100.0%	20.7%	100.0%
2007/2006	156,533	162,713	79,769	383,050
% Reported in 2007	96.2%	100.0%	20.8%	100.0%
2008/2007	188,851	201,473	119,582	591,105
% Reported in 2008	93.7%	100.0%	20.2%	100.0%
2009/2008	194,870	218,405	97,079	433,895
% Reported in 2009	89.2%	100.0%	22.4%	100.0%
2010/2009	354,678	377,018	92,509	392,867
% Reported in 2010	94.1%	100.0%	23.5%	100.0%

Table 7F Comment:

In FY2009, the NICHD Global Network for Women's and Children's Health Research, a large, foreign, Phase 3 Clinical Trial (U01HD040636) expanded enrollment, causing a sharp increase in the aggregate foreign minority enrollment reported in FY2010.

Figure 7c. Phase III Foreign and Domestic Minority Comparison for FY 2002-2010

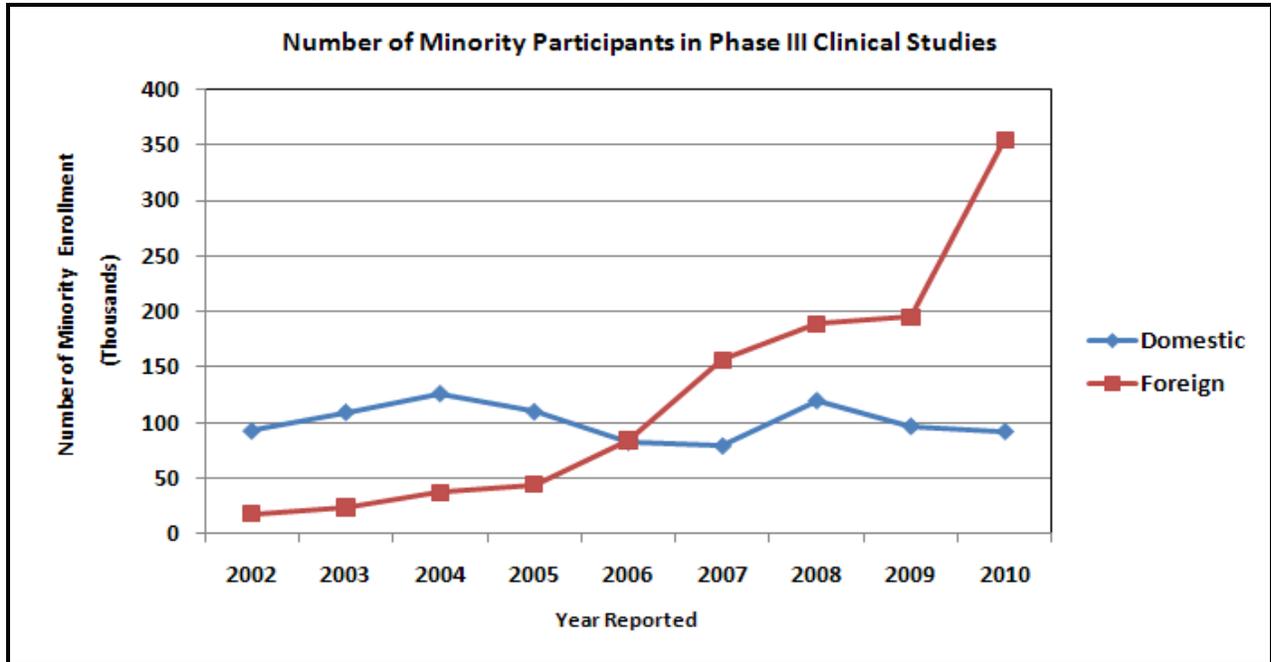


Table 8: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2009: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

Table 8A. PROTOCOLS REPORTED	Total All Clinical Studies*	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Number of Protocols reporting females only	1,356 8.1%	1,069 7.8%	78.8%	131 7.0%	9.7%	149 14.7%	11.0%	7 6.7%	0.5%
Number of Protocols reporting males only	624 3.7%	434 3.2%	69.6%	102 5.5%	16.3%	85 8.4%	13.6%	3 2.9%	0.5%
Number of Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)	9,191 55.1%	7,128 52.0%	77.6%	1,399 75.3%	15.2%	579 57.2%	6.3%	85 81.0%	0.9%
Total Number of Protocols with Enrollment	11,171 66.9%	8,631 63%	77.3%	1,632 87.8%	14.6%	813 80.3%	7.3%	95 90.5%	0.9%
Protocols with zero enrollment (Enrollment data have not yet been submitted)	5,518 33.1%	5,082 37.1%	92.1%	227 12.2%	4.1%	199 19.7%	3.6%	10 9.5%	0.2%
Total Number of Protocols	16,689 100.0%	13,713 100.0%	82.2%	1,859 100.0%	11.1%	1,012 100.0%	6.1%	105 100.0%	0.6%
Total %									

* 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.

Table 8B. ENROLLMENT REPORTED	Total All Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Enrollment in Protocols reporting females only	4,830,093	4,460,062	92.3%	159,063	3.3%	39,730	0.8%	171,238	3.5%
% in Protocols reporting females only	25.2%	28.9%		6.6%		5.3%		32.0%	
Enrollment in Protocols reporting males only	396,076	338,422	85.4%	9,472	2.4%	22,741	5.7%	25,441	6.4%
% in Protocols reporting males only	2.1%	2.2%		0.4%		3.0%		4.8%	
Enrollment in Protocols excluding female-only and male-only enrollment protocols	13,912,569	10,633,061	76.4%	2,247,994	16.2%	693,049	5.0%	338,465	2.4%
% in protocols excluding female-only and male-only enrollment protocols	72.7%	68.9%		93.0%		91.7%		63.2%	
Enrollment Totals for all studies	19,138,738	15,431,545	80.6%	2,416,529	12.6%	755,520	3.9%	535,144	2.8%
Total %	100.0%	100.0%		100.0%		100.0%		100.0%	

Table 8C. MINORITY ENROLLMENT REPORTED**	Total All Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Minority Totals for all studies	5,783,543	4,304,509	74.4%	579,285	10.0%	614,724	10.6%	285,025	4.9%
% Minority enrollment	30.2%	27.9%		24.0%		81.4%		53.3%	

** See Page 4 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%.

Table 9. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

Table 9A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	10,188,246	3,022,938	29.67%
Females (% of total)	62.94%	61.45%	
Males (#)	5,914,676	1,881,416	31.81%
Males (% of total)	36.54%	38.25%	
Unknown (#)	84,143	14,879	17.68%
Unknown (% of total)	0.52%	0.30%	
TOTAL (#)	16,187,065	4,919,233	30.39%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 9,444
--

Table 9B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	91,643	1,090,555	1,073,690	29,381	6,939,461	108,399	728,852	10,061,981
% of total	0.57%	6.83%	6.73%	0.18%	43.48%	0.68%	4.57%	63.05%
<i>% females in each race</i>	0.91%	10.84%	10.67%	0.29%	68.97%	1.08%	7.24%	100.00%
<i>% of each race females</i>	68.59%	69.82%	53.28%	60.09%	62.98%	63.37%	72.24%	63.05%
Males (number)	41,411	469,956	933,867	19,392	4,072,005	61,291	215,172	5,813,094
% of total	0.26%	2.94%	5.85%	0.12%	25.52%	0.38%	1.35%	36.43%
<i>% males in each race</i>	0.71%	8.08%	16.06%	0.33%	70.05%	1.05%	3.70%	100.00%
<i>% of each race males</i>	30.99%	30.09%	46.34%	39.66%	36.95%	35.83%	21.33%	36.43%
Unknown (number)	553	1,387	7,798	123	7,831	1,358	64,951	84,001
% of total	0.00%	0.01%	0.05%	0.00%	0.05%	0.01%	0.41%	0.53%
<i>% unknown in each race</i>	0.66%	1.65%	9.28%	0.15%	9.32%	1.62%	77.32%	100.00%
<i>% of each race unknown</i>	0.41%	0.09%	0.39%	0.25%	0.07%	0.79%	6.44%	0.53%
Total (number)	133,607	1,561,898	2,015,355	48,896	11,019,297	171,048	1,008,975	15,959,076
% of each race in total	0.84%	9.79%	12.63%	0.31%	69.05%	1.07%	6.32%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	8,658,138	728,314	675,529	10,061,981
% of total	54.25%	4.56%	4.23%	63.05%
<i>% females in each race</i>	86.05%	7.24%	6.71%	100.00%
<i>% of each race females</i>	62.89%	61.08%	67.56%	63.05%
Males (number)	5,093,038	459,455	260,601	5,813,094
% of total	31.91%	2.88%	1.63%	36.43%
<i>% males in each race</i>	87.61%	7.90%	4.48%	100.00%
<i>% of each race males</i>	36.99%	38.53%	26.06%	36.43%
Unknown (number)	15,669	4,596	63,736	84,001
% of total	0.10%	0.03%	0.40%	0.53%
<i>% unknown in each race</i>	18.65%	5.47%	75.88%	100.00%
<i>% of each race unknown</i>	0.11%	0.39%	6.37%	0.53%
Total (number)	13,766,845	1,192,365	999,866	15,959,076
% of each race in total	86.26%	7.47%	6.27%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 8,993

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	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
Females (number)	22,861	28,987	29,538	1,701	427,774	33,373	184,098	728,332	3,005,540
% of total	1.92%	2.43%	2.48%	0.14%	35.87%	2.80%	15.44%	61.07%	18.83%
<i>% females in each race</i>	3.14%	3.98%	4.06%	0.23%	58.73%	4.58%	25.28%	100.00%	29.87%
<i>% of each race females</i>	58.60%	54.22%	33.76%	56.53%	63.93%	57.90%	65.09%	61.07%	61.55%
Males (number)	15,986	24,346	57,394	1270	240,495	24,228	95,902	459,621	1,862,314
% of total	1.34%	2.04%	4.81%	0.11%	20.17%	2.03%	8.04%	38.54%	11.67%
<i>% males in each race</i>	3.48%	5.30%	12.49%	0.28%	52.32%	5.27%	20.87%	100.00%	32.04%
<i>% of each race males</i>	40.97%	45.54%	65.59%	42.21%	35.94%	42.03%	33.91%	38.54%	38.14%
Unknown (number)	168	129	566	38	820	39	2,836	4,596	14,875
% of total	0.01%	0.01%	0.05%	0.00%	0.07%	0.00%	0.24%	0.39%	0.09%
<i>% unknown in each race</i>	3.66%	2.81%	12.32%	0.83%	17.84%	0.85%	61.71%	100.00%	17.71%
<i>% of each race unknown</i>	0.43%	0.24%	0.65%	1.26%	0.12%	0.07%	1.00%	0.39%	0.30%
Total (number)	39,015	53,462	87,498	3,009	669,089	57,640	282,836	1,192,549	4,882,729
% of each race in total	3.27%	4.48%	7.34%	0.25%	56.11%	4.83%	23.72%	100.00%	30.60%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 9C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Females (number)	585	2,908	8,926	4,979	102,183	6,684	126,265	17,398
% of total	0.26%	1.28%	3.92%	2.18%	44.82%	2.93%	55.38%	7.63%
<i>% females in each race</i>	0.46%	2.30%	7.07%	3.94%	80.93%	5.29%	100.00%	13.78%
<i>% of each race females</i>	62.77%	59.30%	43.65%	48.72%	57.37%	49.95%	55.38%	47.66%
Males (number)	347	1,994	11,522	5,239	75,906	6,574	101,582	19,102
% of total	0.15%	0.87%	5.05%	2.30%	33.29%	2.88%	44.56%	8.38%
<i>% males in each race</i>	0.34%	1.96%	11.34%	5.16%	74.72%	6.47%	100.00%	18.80%
<i>% of each race males</i>	37.23%	40.66%	56.35%	51.27%	42.62%	49.13%	44.56%	52.33%
Unknown (number)	0	2	1	1	15	123	142	4
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.05%	0.06%	0.00%
<i>% unknown in each race</i>	0.00%	1.41%	0.70%	0.70%	10.56%	86.62%	100.00%	2.82%
<i>% of each race unknown</i>	0.00%	0.04%	0.00%	0.01%	0.01%	0.92%	0.06%	0.01%
Total (number)	932	4,904	20,449	10,219	178,104	13,381	227,989	36,504
% of each race in total	0.41%	2.15%	8.97%	4.48%	78.12%	5.87%	100.00%	16.01%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

**Number of
Protocols with
Enrollment
Data Reported
on Old form:
451**

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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 9A.

Table 10: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2010: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

Table 10A. PROTOCOLS REPORTED	Total All Clinical Studies*	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Number of Protocols reporting females only	1,373	1,089	79.3%	146	10.6%	128	9.3%	10	0.7%
% Protocols reporting females only	8.0%	7.7%		7.6%		11.8%		8.5%	
Number of Protocols reporting males only	691	491	71.1%	111	16.1%	85	12.3%	4	0.6%
% Protocols reporting males only	4.0%	3.5%		5.7%		7.8%		3.4%	
Number of Protocols with Both Female and Male Enrollment (Excluding sex-specific protocols)	10,015	7,945	79.3%	1,407	14.0%	571	5.7%	92	0.9%
% Protocols with Female and Male enrollment	58.1%	56.3%		72.8%		52.7%		78.6%	
Total Number of Protocols with Enrollment	12,079	9,525	78.9%	1,664	13.8%	784	6.5%	106	0.9%
Total %	70.0%	67.0%		86.1%		72.4%		90.6%	
Protocols with zero enrollment (Enrollment data have not yet been submitted)	5,172	4,593	88.8%	269	5.2%	299	5.8%	11	0.2%
% Protocols with zero enrollment	30.0%	32.5%		13.9%		27.6%		9.4%	
Total Number of Protocols	17,251	14,118	81.8%	1,933	11.2%	1,083	6.3%	117	0.7%
Total %	100.0%	100.0%		100.0%		100.0%		100.0%	

* 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.

Table 10B. ENROLLMENT REPORTED		Total All Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
In Protocols reporting females only		4,440,402	4,004,391	90.2%	198,571	4.5%	52,143	1.2%	185,297	4.2%
% in Protocols reporting females only		19.0%	21.1%		7.8%		4.1%		33.0%	
In Protocols reporting males only		1,328,551	1,274,647	95.9%	11,609	0.9%	15,928	1.2%	26,367	2.0%
% in Protocols reporting males only		5.7%	6.7%		0.5%		1.2%		4.7%	
In Protocols excluding female-only and male-only enrollment protocols		17,594,682	13,695,325	77.8%	2,338,533	13.3%	1,210,359	6.9%	350,465	2.0%
% in protocols excluding female-only and male-only enrollment protocols		75.3%	72.2%		91.8%		94.7%		62.3%	
Enrollment Totals for all studies		23,363,635	18,974,363	81.2%	2,548,713	10.9%	1,278,430	5.5%	562,129	2.4%
Total %		100.0%	100.0%		100.0%		100.0%		100.0%	

Table 10C. MINORITY ENROLLMENT REPORTED**		Total All Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Minority Totals for all studies		7,510,763	5,423,294	72.2%	618,237	8.2%	1,165,228	15.5%	304,004	4.0%
% Minority enrollment		32.1%	28.6%		24.3%		91.1%		54.1%	

** See Page 4 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%.

Table 11. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis

Table 11A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	11,758,980	3,970,845	33.77%
Females (% of total)	58.06%	60.27%	
Males (#)	8,344,426	2,577,783	30.89%
Males (% of total)	41.20%	39.13%	
Unknown (#)	149,387	39,894	26.71%
Unknown (% of total)	0.74%	0.61%	
TOTAL (#)	20,252,793	6,588,522	32.53%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 10,309

Table 11B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	200,172	1,280,862	1,443,812	85,453	7,609,654	116,266	975,655	11,711,874
% of total	0.99%	6.36%	7.17%	0.42%	37.77%	0.58%	4.84%	58.12%
<i>% females in each race</i>	1.71%	10.94%	12.33%	0.73%	64.97%	0.99%	8.33%	100.00%
<i>% of each race females</i>	59.21%	69.40%	54.56%	58.11%	56.58%	58.26%	64.08%	58.12%
Males (number)	137,288	561,819	1,192,524	61,491	5,817,603	82,192	436,197	8,289,114
% of total	0.68%	2.79%	5.92%	0.31%	28.87%	0.41%	2.16%	41.14%
<i>% males in each race</i>	1.66%	6.78%	14.39%	0.74%	70.18%	0.99%	5.26%	100.00%
<i>% of each race males</i>	40.61%	30.44%	45.06%	41.82%	43.25%	41.19%	28.65%	41.14%
Unknown (number)	612	2,983	10,087	106	23,225	1,099	110,620	148,732
% of total	0.00%	0.01%	0.05%	0.00%	0.12%	0.01%	0.55%	0.74%
<i>% unknown in each race</i>	0.41%	2.01%	6.78%	0.07%	15.62%	0.74%	74.38%	100.00%
<i>% of each race unknown</i>	0.18%	0.16%	0.38%	0.07%	0.17%	0.55%	7.27%	0.74%
Total (number)	338,072	1,845,664	2,646,423	147,050	13,450,482	199,557	1,522,472	20,149,720
% of each race in total	1.68%	9.16%	13.13%	0.73%	66.75%	0.99%	7.56%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	9,649,854	1,055,739	1,006,281	11,711,874
% of total	47.89%	5.24%	4.99%	58.12%
<i>% females in each race</i>	82.39%	9.01%	8.59%	100.00%
<i>% of each race females</i>	58.11%	57.52%	58.91%	58.12%
Males (number)	6,936,676	752,923	599,515	8,289,114
% of total	34.43%	3.74%	2.98%	41.14%
<i>% males in each race</i>	83.68%	9.08%	7.23%	100.00%
<i>% of each race males</i>	41.77%	41.02%	35.10%	41.14%
Unknown (number)	19,792	26,675	102,265	148,732
% of total	0.10%	0.13%	0.51%	0.74%
<i>% unknown in each race</i>	13.31%	17.93%	68.76%	100.00%
<i>% of each race unknown</i>	0.12%	1.45%	5.99%	0.74%
Total (number)	16,606,322	1,835,337	1,708,061	20,149,720
% of each race in total	82.41%	9.11%	8.48%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 10,139

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	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
Females (number)	109,588	6,372	68,868	1,526	564,744	31,912	272,729	1,055,739	3,964,038
% of total	5.97%	0.35%	3.75%	0.08%	30.77%	1.74%	14.86%	57.52%	19.67%
<i>% females in each race</i>	10.38%	0.60%	6.52%	0.14%	53.49%	3.02%	25.83%	100.00%	33.85%
<i>% of each race females</i>	54.01%	65.41%	41.37%	56.06%	59.36%	52.20%	61.85%	57.52%	60.34%
Males (number)	93,129	3,170	96,463	1,147	372,988	28,968	157,058	752,923	2,565,360
% of total	5.07%	0.17%	5.26%	0.06%	20.32%	1.58%	8.56%	41.02%	12.73%
<i>% males in each race</i>	12.37%	0.42%	12.81%	0.15%	49.54%	3.85%	20.86%	100.00%	30.95%
<i>% of each race males</i>	45.90%	32.54%	57.95%	42.14%	39.20%	47.39%	35.62%	41.02%	39.05%
Unknown (number)	175	199	1,134	49	1,373	250	11,135	26,675	39,755
% of total	0.01%	0.01%	0.06%	0.00%	0.75%	0.01%	0.61%	1.45%	0.20%
<i>% unknown in each race</i>	0.66%	0.75%	4.25%	0.18%	51.48%	0.94%	41.74%	100.00%	26.73%
<i>% of each race unknown</i>	0.09%	2.04%	0.68%	1.80%	1.44%	0.41%	2.53%	1.45%	0.61%
Total (number)	202,892	9,741	166,465	2,722	951,465	61,130	440,922	1,835,337	6,569,153
% of each race in total	11.05%	0.53%	9.07%	0.15%	51.84%	3.33%	24.02%	100.00%	32.60%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 11C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 170
Females (number)	185	978	2,745	2,899	38,859	1,440	47,106	6,807	
% of total	0.18%	0.95%	2.66%	2.81%	37.70%	1.40%	45.70%	6.60%	
<i>% females in each race</i>	0.39%	2.08%	5.83%	6.15%	82.49%	3.06%	100.00%	14.45%	
<i>% of each race females</i>	49.47%	46.02%	27.26%	42.64%	48.19%	47.06%	45.70%	35.14%	
Males (number)	189	1,075	7,284	3,875	41,381	1,508	55,312	12,423	
% of total	0.18%	1.04%	7.07%	3.76%	40.15%	1.46%	53.66%	12.05%	
<i>% males in each race</i>	0.34%	1.94%	13.17%	7.01%	74.81%	2.73%	100.00%	22.46%	
<i>% of each race males</i>	50.53%	50.59%	72.33%	56.99%	51.31%	49.28%	53.66%	64.14%	
Unknown (number)	0	72	42	25	404	112	655	139	
% of total	0.00%	0.07%	0.04%	0.02%	0.39%	0.11%	0.64%	0.13%	
<i>% unknown in each race</i>	0.00%	10.99%	6.41%	3.82%	61.68%	17.10%	100.00%	21.22%	
<i>% of each race unknown</i>	0.00%	3.39%	0.42%	0.37%	0.50%	3.66%	0.64%	0.72%	
Total (number)	374	2,125	10,071	6,799	80,644	3,060	103,073	19,369	
% of each race in total	0.36%	2.06%	9.77%	6.60%	78.24%	2.97%	100.00%	18.79%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 11A.

Table 12. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

Table 12A. SUMMARY TOTALS: Old Form + New Form

Sex/Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	5,688,454	1,759,483	30.93%
Females (% of total)	50.22%	49.89%	
Males (#)	5,553,513	1,752,572	31.56%
Males (% of total)	49.03%	49.69%	
Unknown (#)	84,143	14,879	17.68%
Unknown (% of total)	0.74%	0.42%	
TOTAL (#)	11,326,110	3,526,934	31.14%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 7,707

Table 12B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards
I. Total of All Subjects by Race

Sex/Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	44,382	433,527	816,068	26,622	4,011,827	75,247	226,437	5,634,110
% of total	0.40%	3.87%	7.28%	0.24%	35.77%	0.67%	2.02%	50.23%
<i>% females in each race</i>	0.79%	7.69%	14.48%	0.47%	71.21%	1.34%	4.02%	100.00%
<i>% of each race females</i>	51.75%	52.20%	47.38%	57.97%	50.82%	55.27%	45.23%	50.23%
Males (number)	40,828	395,569	898,353	19,179	3,875,190	59,547	209,270	5,497,936
% of total	0.36%	3.53%	8.01%	0.17%	34.55%	0.53%	1.87%	49.02%
<i>% males in each race</i>	0.74%	7.19%	16.34%	0.35%	70.48%	1.08%	3.81%	100.00%
<i>% of each race males</i>	47.61%	47.63%	52.16%	41.76%	49.09%	43.74%	41.80%	49.02%
Unknown (number)	553	1,387	7,798	123	7,831	1,358	64,951	84,001
% of total	0.00%	0.01%	0.07%	0.00%	0.07%	0.01%	0.58%	0.75%
<i>% unknown in each race</i>	0.66%	1.65%	9.28%	0.15%	9.32%	1.62%	77.32%	100.00%
<i>% of each race unknown</i>	0.64%	0.17%	0.45%	0.27%	0.10%	1.00%	12.97%	0.75%
Total (number)	85,763	830,483	1,722,219	45,924	7,894,848	136,152	500,658	11,216,047
% of each race in total	0.76%	7.40%	15.35%	0.41%	70.39%	1.21%	4.46%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	4,980,970	449,485	203,655	5,634,110
% of total	44.41%	4.01%	1.82%	50.23%
<i>% females in each race</i>	88.41%	7.98%	3.61%	100.00%
<i>% of each race females</i>	50.55%	49.79%	44.38%	50.23%
Males (number)	4,857,833	448,637	191,466	5,497,936
% of total	43.31%	4.00%	1.71%	49.02%
<i>% males in each race</i>	88.36%	8.16%	3.48%	100.00%
<i>% of each race males</i>	49.30%	49.70%	41.73%	49.02%
Unknown (number)	15,669	4,596	63,736	84,001
% of total	0.14%	0.04%	0.57%	0.75%
<i>% unknown in each race</i>	18.65%	5.47%	75.88%	100.00%
<i>% of each race unknown</i>	0.16%	0.51%	13.89%	0.75%
Total (number)	9,854,472	902,718	458,857	11,216,047
% of each race in total	87.86%	8.05%	4.09%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 7,404

III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
 Total of All Hispanic or Latino Subjects by Race

Sex/ Gender	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
Females (number)	16,377	25,246	25,141	1,408	259,664	25,744	95,923	449,503	1,751,433
% of total	1.81%	2.80%	2.78%	0.16%	28.76%	2.85%	10.62%	49.78%	15.62%
<i>% females in each race</i>	3.64%	5.62%	5.59%	0.31%	57.77%	5.73%	21.34%	100.00%	31.09%
<i>% of each race females</i>	50.72%	50.80%	30.49%	52.13%	52.10%	54.81%	50.37%	49.78%	49.91%
Males (number)	15,741	24,322	56,761	1,255	237,869	21,183	91,672	448,803	1,743,017
% of total	1.74%	2.69%	6.29%	0.14%	26.34%	2.35%	10.15%	49.71%	15.54%
<i>% males in each race</i>	3.51%	5.42%	12.65%	0.28%	53.00%	4.72%	20.43%	100.00%	31.70%
<i>% of each race males</i>	48.75%	48.94%	68.83%	46.46%	47.73%	45.10%	48.14%	49.71%	49.67%
Unknown (number)	168	129	566	38	820	39	2,836	4,596	14,875
% of total	0.02%	0.01%	0.06%	0.00%	0.09%	0.00%	0.31%	0.51%	0.13%
<i>% unknown in each race</i>	3.66%	2.81%	12.32%	0.83%	17.84%	0.85%	61.71%	100.00%	17.71%
<i>% of each race unknown</i>	0.52%	0.26%	0.69%	1.41%	0.16%	0.08%	1.49%	0.51%	0.42%
Total (number)	32,286	49,697	82,468	2,701	498,353	46,966	190,431	902,902	3,509,325
% of each race in total	3.58%	5.50%	9.13%	0.30%	55.19%	5.20%	21.09%	100.00%	31.29%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 12C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 303
Females (number)	303	1,343	4,259	2,145	40,823	5,471	54,344	8,050	303
% of total	0.28%	1.22%	3.87%	1.95%	37.09%	4.97%	49.38%	7.31%	
<i>% females in each race</i>	0.56%	2.47%	7.84%	3.95%	75.12%	10.07%	100.00%	14.81%	
<i>% of each race females</i>	60.97%	48.66%	44.95%	43.99%	49.91%	51.36%	49.38%	45.72%	
Males (number)	194	1,415	5,216	2,730	40,963	5,059	55,577	9,555	
% of total	0.18%	1.29%	4.74%	2.48%	37.22%	4.60%	50.50%	8.68%	
<i>% males in each race</i>	0.35%	2.55%	9.39%	4.91%	73.70%	9.10%	100.00%	17.19%	
<i>% of each race males</i>	39.03%	51.27%	55.04%	55.99%	50.08%	47.49%	50.50%	54.26%	
Unknown (number)	0	2	1	1	15	123	142	4	
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.11%	0.13%	0.00%	
<i>% unknown in each race</i>	0.00%	1.41%	0.70%	0.70%	10.56%	86.62%	100.00%	2.82%	
<i>% of each race unknown</i>	0.00%	0.07%	0.01%	0.02%	0.02%	1.15%	0.13%	0.02%	
Total (number)	497	2,760	9,476	4,876	81,801	10,653	110,063	17,609	
% of each race in total	0.45%	2.51%	8.61%	4.43%	74.32%	9.68%	100.00%	16.00%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 12A.

Table 13A. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis

Table 13A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	7,702,446	2,677,903	34.77%
Females (% of total)	51.67%	52.65%	
Males (#)	7,053,851	2,368,203	33.57%
Males (% of total)	47.32%	46.56%	
Unknown (#)	149,387	39,894	26.71%
Unknown (% of total)	1.00%	0.78%	
TOTAL (#)	14,905,684	5,086,000	34.12%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 8,516

Table 13B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	155,136	622,191	1,146,324	83,175	5,110,922	89,055	481,207	7,688,010
% of total	1.04%	4.18%	7.71%	0.56%	34.37%	0.60%	3.24%	51.69%
<i>% females in each race</i>	2.02%	8.09%	14.91%	1.08%	66.48%	1.16%	6.26%	100.00%
<i>% of each race females</i>	53.69%	55.94%	50.81%	57.55%	51.63%	54.40%	47.81%	51.69%
Males (number)	133,215	487,148	1,099,558	61,237	4,765,892	73,550	414,770	7,035,370
% of total	0.90%	3.28%	7.39%	0.41%	32.05%	0.49%	2.79%	47.31%
<i>% males in each race</i>	1.89%	6.92%	15.63%	0.87%	67.74%	1.05%	5.90%	100.00%
<i>% of each race males</i>	46.10%	43.80%	48.74%	42.37%	48.14%	44.93%	41.21%	47.31%
Unknown (number)	612	2,983	10,087	106	23,225	1,099	110,620	148,732
% of total	0.00%	0.02%	0.07%	0.00%	0.16%	0.01%	0.74%	1.00%
<i>% unknown in each race</i>	0.41%	2.01%	6.78%	0.07%	15.62%	0.74%	74.38%	100.00%
<i>% of each race unknown</i>	0.21%	0.27%	0.45%	0.07%	0.23%	0.67%	10.99%	1.00%
Total (number)	288,963	1,112,322	2,255,969	144,518	9,900,039	163,704	1,006,597	14,872,112
% of each race in total	1.94%	7.48%	15.17%	0.97%	66.57%	1.10%	6.77%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown / Not Reported	Total
Females (number)	6,499,513	779,245	409,252	7,688,010
% of total	43.70%	5.24%	2.75%	51.69%
<i>% females in each race</i>	84.54%	10.14%	5.32%	100.00%
<i>% of each race females</i>	52.49%	50.97%	42.57%	51.69%
Males (number)	5,862,747	722,809	449,814	7,035,370
% of total	39.42%	4.86%	3.02%	47.31%
<i>% males in each race</i>	83.33%	10.27%	6.39%	100.00%
<i>% of each race males</i>	47.35%	47.28%	46.79%	47.31%
Unknown (number)	19,792	26,675	102,265	148,732
% of total	0.13%	0.18%	0.69%	1.00%
<i>% unknown in each race</i>	13.31%	17.93%	68.76%	100.00%
<i>% of each race unknown</i>	0.16%	1.74%	10.64%	1.00%
Total (number)	12,382,052	1,528,729	961,331	14,872,112
% of each race in total	83.26%	10.28%	6.46%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 8,397

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	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
Females (number)	105,387	3,469	64,946	1,238	396,565	25,411	182,229	779,245	2,674,675
% of total	6.89%	0.23%	4.25%	0.08%	25.94%	1.66%	11.92%	50.97%	17.98%
<i>% females in each race</i>	13.52%	0.45%	8.33%	0.16%	50.89%	3.26%	23.39%	100.00%	34.79%
<i>% of each race females</i>	53.27%	50.97%	40.39%	51.20%	51.75%	52.84%	52.61%	50.97%	52.67%
Males (number)	92,284	3,138	94,730	1131	356,065	22,429	153,032	722,809	2,363,805
% of total	6.04%	0.21%	6.20%	0.07%	23.29%	1.47%	10.01%	47.28%	15.89%
<i>% males in each race</i>	12.77%	0.43%	13.11%	0.16%	49.26%	3.10%	21.17%	100.00%	33.60%
<i>% of each race males</i>	46.64%	46.11%	58.91%	46.77%	46.46%	46.64%	44.18%	47.28%	46.55%
Unknown (number)	175	199	1134	49	13733	250	11,135	26,675	39,755
% of total	0.01%	0.01%	0.07%	0.00%	0.90%	0.02%	0.73%	1.74%	0.27%
<i>% unknown in each race</i>	0.66%	0.75%	4.25%	0.18%	51.48%	0.94%	41.74%	100.00%	26.73%
<i>% of each race unknown</i>	0.09%	2.92%	0.71%	2.03%	1.79%	0.52%	3.21%	1.74%	0.78%
Total (number)	197,846	6,806	160,810	2,418	766,363	48,090	346,396	1,528,729	5,078,235
% of each race in total	12.94%	0.45%	10.52%	0.16%	50.13%	3.15%	22.66%	100.00%	34.15%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 13C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 119
Females (number)	51	485	1,457	1,235	10,067	1,141	14,436	3,228	
% of total	0.15%	1.44%	4.34%	3.68%	29.99%	3.40%	43.00%	9.62%	
<i>% females in each race</i>	0.35%	3.36%	10.09%	8.56%	69.74%	7.90%	100.00%	22.36%	
<i>% of each race females</i>	42.86%	42.36%	39.73%	43.58%	43.31%	44.48%	43.00%	41.57%	
Males (number)	68	588	2,168	1,574	12,771	1,312	18,481	4,398	
% of total	0.20%	1.75%	6.46%	4.69%	38.04%	3.91%	55.05%	13.10%	
<i>% males in each race</i>	0.37%	3.18%	11.73%	8.52%	69.10%	7.10%	100.00%	23.80%	
<i>% of each race males</i>	57.14%	51.35%	59.12%	55.54%	54.95%	51.15%	55.05%	56.64%	
Unknown (number)	0	72	42	25	404	112	655	139	
% of total	0.00%	0.21%	0.13%	0.07%	1.20%	0.33%	1.95%	0.41%	
<i>% unknown in each race</i>	0.00%	10.99%	6.41%	3.82%	61.68%	17.10%	100.00%	21.22%	
<i>% of each race unknown</i>	0.00%	6.29%	1.15%	0.88%	1.74%	4.37%	1.95%	1.79%	
Total (number)	119	1,145	3,667	2,834	23,242	2,565	33,572	7,765	
% of each race in total	0.35%	3.41%	10.92%	8.44%	69.23%	7.64%	100.00%	23.13%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 13A.

Table 14. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2009: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

Table 14A. PROTOCOLS REPORTED	Total of Phase III Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Number of Protocols reporting females only	151	94	62.3%	2	1.3%	54	35.8%	1	0.8%
% Protocols reporting females only	22.8%	21.4%		5.1%		30.2%		25.0%	
Number of Protocols reporting males only	48	25	52.1%	2	4.2%	21	43.8%	0	0.0%
% Protocols reporting males only	7.3%	5.7%		5.1%		11.7%		0.0%	
Number of Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)	431	298	69.1%	30	7.0%	100	23.2%	3	0.7%
% Protocols with Female and Male enrollment	65.1%	67.7%		76.9%		55.9%		75.0%	
Total Number of Protocols with Enrollment	630	417	66.2%	34	5.4%	175	27.8%	4	0.6%
Total %	95.2%	95%		87.2%		97.8%		100.0%	
Phase III Protocols with zero enrollment (Enrollment data have not yet been submitted)	32	23	71.9%	5	15.6%	4	12.5%	0	0.0%
% Protocols with zero enrollment	4.8%	5.2%		12.8%		2.2%		0.0%	
Total Number of Phase III Protocols	662	440	66.5%	39	5.9%	179	27.0%	4	0.6%
Total %	100.0%	100.0%		100.0%		100.0%		100.0%	

* 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.

Table 14B. ENROLLMENT REPORTED										
	Total of Phase III Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols	
In Protocols reporting females only	141,892	123,187	86.8%	5	0.0%	11,234	7.9%	7,466	5.3%	
% in Protocols reporting females only	21.8%	28.8%		0.1%		5.4%		71.3%		
In Protocols reporting males only	65,516	59,488	90.8%	155	0.2%	5,873	9.0%	0	0.0%	
% in Protocols reporting males only	10.0%	13.9%		2.6%		2.8%		0.0%		
In Protocols excluding female-only and male-only enrollment protocols	444,892	245,220	55.1%	5,840	1.3%	190,823	42.9%	3,009	0.7%	
% in protocols excluding female-only and male-only enrollment protocols	68.2%	57.3%		97.3%		91.8%		28.7%		
Enrollment Totals for all studies	652,300	427,895	65.6%	6,000	0.92%	207,930	31.88%	10,475	1.6%	
Total %	100.0%	100.0%		100.0%		100.0%		100.0%		

14C. MINORITY ENROLLMENT REPORTED**										
	Total of Phase III Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols	
Minority Total for all Phase III studies	291,949	95,512	32.7%	1,567	0.5%	187,194	64.1%	7,676	2.6%	
% Minority Enrollment	44.8%	22.3%		26.1%		90.0%		73.3%		

** See Page 4 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%.

**Table 15. Aggregate Enrollment Data for Extramural Phase III Research
Funded in FY2008 and Reported in FY2009: Percent Analysis**

Table 15A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	334,429	149,550	44.72%
Females (% of total)	52.60%	52.90%	
Males (#)	271,016	132,454	48.87%
Males (% of total)	42.62%	46.85%	
Unknown (#)	30,380	702	2.31%
Unknown (% of total)	4.78%	0.25%	
TOTAL (#)	635,825	282,706	44.46%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 592
--

Table 15B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	9,746	47,842	61,229	438	106,737	2,281	14,361	242,634
% of total	2.06%	10.11%	12.94%	0.09%	22.56%	0.48%	3.04%	51.28%
<i>% females in each race</i>	4.02%	19.72%	25.24%	0.18%	43.99%	0.94%	5.92%	100.00%
<i>% of each race females</i>	56.23%	51.53%	53.13%	51.05%	56.50%	48.82%	26.96%	51.28%
Males (number)	7,528	44,893	53,855	416	80,993	2,332	10,134	200,151
% of total	1.59%	9.49%	11.38%	0.09%	17.12%	0.49%	2.14%	42.30%
<i>% males in each race</i>	3.76%	22.43%	26.91%	0.21%	40.47%	1.17%	5.06%	100.00%
<i>% of each race males</i>	43.43%	48.35%	46.73%	48.48%	42.88%	49.91%	19.02%	42.30%
Unknown (number)	59	108	168	4	1,169	59	28,776	30,343
% of total	0.01%	0.02%	0.04%	0.00%	0.25%	0.01%	6.08%	6.41%
<i>% unknown in each race</i>	0.19%	0.36%	0.55%	0.01%	3.85%	0.19%	94.84%	100.00%
<i>% of each race unknown</i>	0.34%	0.12%	0.15%	0.47%	0.62%	1.26%	54.02%	6.41%
Total (number)	17,333	92,843	115,252	858	188,899	4,672	53,271	473,128
% of each race in total	3.66%	19.62%	24.36%	0.18%	39.93%	0.99%	11.26%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	209,663	26,804	6,167	242,634
% of total	44.31%	5.67%	1.30%	51.28%
<i>% females in each ethnicity</i>	86.41%	11.05%	2.54%	100.00%
<i>% of each ethnicity females</i>	53.85%	60.18%	15.72%	51.28%
Males (number)	178,242	17,354	4,555	200,151
% of total	37.67%	3.67%	0.96%	42.30%
<i>% males in each ethnicity</i>	89.05%	8.67%	2.28%	100.00%
<i>% of each ethnicity males</i>	45.78%	38.97%	11.61%	42.30%
Unknown (number)	1,449	379	28,515	30,343
% of total	0.31%	0.08%	6.03%	6.41%
<i>% unknown in each ethnicity</i>	4.78%	1.25%	93.98%	100.00%
<i>% of each ethnicity unknown</i>	0.37%	0.85%	72.67%	6.41%
Total (number)	389,354	44,537	39,237	473,128
% of each ethnicity in total	82.29%	9.41%	8.29%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 407

III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race

Sex/ Gender	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
Females (number)	8,728	138	488	99	7,263	431	9,657	26,804	138,456
% of total	19.60%	0.31%	1.10%	0.22%	16.31%	0.97%	21.68%	60.18%	29.26%
<i>% females in each race</i>	32.56%	0.51%	1.82%	0.37%	27.10%	1.61%	36.03%	100.00%	57.06%
<i>% of each race females</i>	57.00%	39.32%	52.08%	50.00%	63.24%	44.71%	63.15%	60.18%	53.72%
Males (number)	6,543	203	439	95	4,159	521	5,394	17,354	118,577
% of total	14.69%	0.46%	0.99%	0.21%	9.34%	1.17%	12.11%	38.97%	25.06%
<i>% males in each race</i>	37.70%	1.17%	2.53%	0.55%	23.97%	3.00%	31.08%	100.00%	59.24%
<i>% of each race males</i>	42.73%	57.83%	46.85%	47.98%	36.22%	54.05%	35.28%	38.97%	46.01%
Unknown (number)	41	10	10	4	62	12	240	379	700
% of total	0.09%	0.02%	0.02%	0.01%	0.14%	0.03%	0.54%	0.85%	0.15%
<i>% unknown in each race</i>	10.82%	2.64%	2.64%	1.06%	16.36%	3.17%	63.32%	100.00%	2.31%
<i>% of each race unknown</i>	0.27%	2.85%	1.07%	2.02%	0.54%	1.24%	1.57%	0.85%	0.27%
Total (number)	15,312	351	937	198	11,484	964	15,291	44,537	257,733
% of each race in total	34.38%	0.79%	2.10%	0.44%	25.79%	2.16%	34.33%	100.00%	54.47%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 15C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 185
Females (number)	351	2,094	6,053	2,596	78,830	1,871	91,795	11,094	
% of total	0.22%	1.29%	3.72%	1.60%	48.45%	1.15%	56.42%	6.82%	
<i>% females in each race</i>	0.38%	2.28%	6.59%	2.83%	85.88%	2.04%	100.00%	12.09%	
<i>% of each race females</i>	57.64%	64.85%	41.09%	40.53%	59.08%	43.64%	56.42%	44.42%	
Males (number)	258	1,134	8,676	3,809	54,596	2,392	70,865	13,877	
% of total	0.16%	0.70%	5.33%	2.34%	33.56%	1.47%	43.56%	8.53%	
<i>% males in each race</i>	0.36%	1.60%	12.24%	5.38%	77.04%	3.38%	100.00%	19.58%	
<i>% of each race males</i>	42.36%	35.12%	58.90%	59.47%	40.92%	55.80%	43.56%	55.57%	
Unknown (number)	0	1	1	0	11	24	37	2	
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.02%	0.00%	
<i>% unknown in each race</i>	0.00%	2.70%	2.70%	0.00%	29.73%	64.86%	100.00%	5.41%	
<i>% of each race unknown</i>	0.00%	0.03%	0.01%	0.00%	0.01%	0.56%	0.02%	0.01%	
Total (number)	609	3,229	14,730	6,405	133,437	4,287	162,697	24,973	
% of each race in total	0.37%	1.98%	9.05%	3.94%	82.02%	2.63%	100.00%	15.35%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 15A.

Table 16. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2010: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

Table 16A. PROTOCOLS REPORTED	Total of Phase III Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Number of Protocols reporting females only	140	93	66.4%	6	4.3%	40	28.6%	1	0.8%
% Protocols reporting females only	18.8%	17.3%		14.0%		25.2%		25.0%	
Number of Protocols reporting males only	61	32	52.5%	5	8.2%	24	39.3%	0	0.0%
% Protocols reporting males only	8.2%	6.0%		11.6%		15.1%		0.0%	
Number of Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)	495	373	75.4%	31	6.3%	88	17.8%	3	0.6%
% Protocols with Female and Male enrollment	66.6%	69.5%		72.1%		55.3%		75.0%	
Total Number of Protocols with Enrollment	696	498	71.6%	42	6.0%	152	21.8%	4	0.6%
Total %	93.7%	93%		97.7%		95.6%		100.0%	
Phase III Protocols with zero enrollment (Enrollment data have not yet been submitted)	47	39	83.0%	1	2.1%	7	14.9%	0	0.0%
% Protocols with zero enrollment	6.3%	7.3%		2.3%		4.4%		0.0%	
Total Number of Phase III Protocols	743	537	72.3%	43	5.8%	159	21.4%	4	0.5%
Total %	100.0%	100.0%		100.0%		100.0%		100.0%	

* 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.

Table 16B. ENROLLMENT REPORTED		Total of Phase III Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
In Protocols reporting females only		119,103	84,405	70.9%	5,095	4.3%	22,137	18.6%	7,466	6.3%
% in Protocols reporting females only		15.5%	22.0%		51.6%		6.0%		71.1%	
In Protocols reporting males only		62,315	56,117	90.1%	164	0.3%	6,034	9.7%	0	0.0%
% in Protocols reporting males only		8.1%	14.7%		1.7%		1.6%		0.0%	
In Protocols excluding female-only and male-only enrollment protocols		588,467	242,476	41.2%	4,610	0.8%	338,349	57.5%	3,032	0.5%
% in protocols excluding female-only and male-only enrollment protocols		76.4%	63.3%		46.7%		92.3%		28.9%	
Enrollment Totals for all studies		769,885	382,998	49.7%	9,869	1.28%	366,520	47.61%	10,498	1.4%
Total %		100.0%	100.0%		100.0%		100.0%		100.0%	

Table 16C. MINORITY ENROLLMENT REPORTED**		Total of Phase III Clinical Studies	Domestic Extramural Protocols	% Domestic Extramural Protocols	Domestic Intramural Protocols	% Domestic Intramural Protocols	Foreign Extramural Protocols	% Foreign Extramural Protocols	Foreign Intramural Protocols	% Foreign Intramural Protocols
Minority Total for all Phase III studies		447,187	89,006	19.9%	3,503	0.8%	346,979	77.6%	7,699	1.7%
Total %		58.1%	23.2%		35.5%		94.7%		73.3%	

** See Page 4 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%.

Table 17. Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis

Table 17A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	392,053	240,290	61.29%
Females (% of total)	52.31%	55.11%	
Males (#)	326,582	194,486	59.55%
Males (% of total)	43.57%	44.61%	
Unknown (#)	30,883	1,209	3.91%
Unknown (% of total)	4.12%	0.28%	
TOTAL (#)	749,518	435,985	58.17%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 650

Table 17B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	7,735	62,107	141,753	482	125,544	3,122	18,294	359,037
% of total	1.15%	9.21%	21.03%	0.07%	18.62%	0.46%	2.71%	53.26%
<i>% females in each race</i>	2.15%	17.30%	39.48%	0.13%	34.97%	0.87%	5.10%	100.00%
<i>% of each race females</i>	49.70%	55.04%	56.21%	51.55%	55.66%	37.83%	31.10%	53.26%
Males (number)	7,770	50,641	109,659	449	99,388	5,071	11,248	284,226
% of total	1.15%	7.51%	16.27%	0.07%	14.74%	0.75%	1.67%	42.16%
<i>% males in each race</i>	2.73%	17.82%	38.58%	0.16%	34.97%	1.78%	3.96%	100.00%
<i>% of each race males</i>	49.93%	44.88%	43.49%	48.02%	44.06%	61.44%	19.12%	42.16%
Unknown (number)	57	95	762	4	622	60	29,279	30,879
% of total	0.01%	0.01%	0.11%	0.00%	0.09%	0.01%	4.34%	4.58%
<i>% unknown in each race</i>	0.18%	0.31%	2.47%	0.01%	2.01%	0.19%	94.82%	100.00%
<i>% of each race unknown</i>	0.37%	0.08%	0.30%	0.43%	0.28%	0.73%	49.78%	4.58%
Total (number)	15,562	112,843	252,174	935	225,554	8,253	58,821	674,142
% of each race in total	2.31%	16.74%	37.41%	0.14%	33.46%	1.22%	8.73%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	319,083	30,441	9,513	359,037
% of total	47.33%	4.52%	1.41%	53.26%
<i>% females in each ethnicity</i>	88.87%	8.48%	2.65%	100.00%
<i>% of each ethnicity females</i>	55.44%	57.61%	20.80%	53.26%
Males (number)	254,960	22,090	7,176	284,226
% of total	37.82%	3.28%	1.06%	42.16%
<i>% males in each ethnicity</i>	89.70%	7.77%	2.52%	100.00%
<i>% of each ethnicity males</i>	44.30%	41.80%	15.69%	42.16%
Unknown (number)	1,516	311	29,052	30,879
% of total	0.22%	0.05%	4.31%	4.58%
<i>% unknown in each ethnicity</i>	4.91%	1.01%	94.08%	100.00%
<i>% of each ethnicity unknown</i>	0.26%	0.59%	63.51%	4.58%
Total (number)	575,559	52,842	45,741	674,142
% of each ethnicity in total	85.38%	7.84%	6.79%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 599

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	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
Females (number)	6,516	144	565	104	9,497	642	12,973	30,441	237,669
% of total	12.33%	0.27%	1.07%	0.20%	17.97%	1.21%	24.55%	57.61%	35.26%
<i>% females in each race</i>	21.41%	0.47%	1.86%	0.34%	31.20%	2.11%	42.62%	100.00%	66.20%
<i>% of each race females</i>	49.70%	40.00%	52.51%	50.98%	62.53%	20.70%	65.51%	57.61%	55.95%
Males (number)	6,553	206	501	96	5,644	2,444	6,646	22,090	185,880
% of total	12.40%	0.39%	0.95%	0.18%	10.68%	4.63%	12.58%	41.80%	27.57%
<i>% males in each race</i>	29.67%	0.93%	2.27%	0.43%	25.55%	11.06%	30.09%	100.00%	65.40%
<i>% of each race males</i>	49.98%	57.22%	46.56%	47.06%	37.16%	78.81%	33.56%	41.80%	43.76%
Unknown (number)	41	10	10	4	46	15	185	311	1,209
% of total	0.08%	0.02%	0.02%	0.01%	0.09%	0.03%	0.35%	0.59%	0.18%
<i>% unknown in each race</i>	13.18%	3.22%	3.22%	1.29%	14.79%	4.82%	59.49%	100.00%	3.92%
<i>% of each race unknown</i>	0.31%	2.78%	0.93%	1.96%	0.30%	0.48%	0.93%	0.59%	0.28%
Total (number)	13,110	360	1,076	204	15,187	3,101	19,804	52,842	424,758
% of each race in total	24.81%	0.68%	2.04%	0.39%	28.74%	5.87%	37.48%	100.00%	63.01%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 17C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 51
Females (number)	141	544	1,234	702	30,036	359	33,016	2,621	
% of total	0.19%	0.72%	1.64%	0.93%	39.85%	0.48%	43.80%	3.48%	
<i>% females in each race</i>	0.43%	1.65%	3.74%	2.13%	90.97%	1.09%	100.00%	7.94%	
<i>% of each race females</i>	48.45%	48.18%	18.53%	22.29%	47.36%	49.45%	43.80%	23.35%	
Males (number)	150	585	5,424	2,447	33,384	366	42,356	8,606	
% of total	0.20%	0.78%	7.20%	3.25%	44.29%	0.49%	56.19%	11.42%	
<i>% males in each race</i>	0.35%	1.38%	12.81%	5.78%	78.82%	0.86%	100.00%	20.32%	
<i>% of each race males</i>	51.55%	51.82%	81.47%	77.71%	52.64%	50.41%	56.19%	76.65%	
Unknown (number)	0	0	0	0	3	1	4	0	
% of total	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	
<i>% unknown in each race</i>	0.00%	0.00%	0.00%	0.00%	75.00%	25.00%	100.00%	0.00%	
<i>% of each race unknown</i>	0.00%	0.00%	0.00%	0.00%	0.00%	0.14%	0.01%	0.00%	
Total (number)	291	1,129	6,658	3,149	63,423	726	75,376	11,227	
% of each race in total	0.39%	1.50%	8.83%	4.18%	84.14%	0.96%	100.00%	14.89%	
Total (%)	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)
 Plain Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)
 Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 17A.

Table 18. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

Table 18A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority by Enrollment
Females (#)	1,250,897	416,054	33.26%
Females (% of total)	42.38%	48.14%	
Males (#)	1,655,970	443,986	26.81%
Males (% of total)	56.10%	51.37%	
Unknown (#)	44,806	4,270	9.53%
Unknown (% of total)	1.52%	0.49%	
TOTAL (#)	2,951,673	864,310	29.28%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 1,727
--

Table 18B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	9,820	176,141	72,500	654	740,001	78,852	90,893	1,168,861
% of total	0.35%	6.31%	2.60%	0.02%	26.52%	2.83%	3.26%	41.89%
<i>% females in each race</i>	0.84%	15.07%	6.20%	0.06%	63.31%	6.75%	7.78%	100.00%
<i>% of each race females</i>	46.97%	63.21%	26.63%	45.32%	41.77%	51.61%	31.07%	41.89%
Males (number)	11,064	102,131	195,873	789	1,020,111	73,920	172,687	1,576,575
% of total	0.40%	3.66%	7.02%	0.03%	36.56%	2.65%	6.19%	56.50%
<i>% males in each race</i>	0.70%	6.48%	12.42%	0.05%	64.70%	4.69%	10.95%	100.00%
<i>% of each race males</i>	52.92%	36.65%	71.95%	54.68%	57.58%	48.38%	59.03%	56.50%
Unknown (number)	24	369	3,849	0	11,536	19	28,963	44,760
% of total	0.00%	0.01%	0.14%	0.00%	0.41%	0.00%	1.04%	1.60%
<i>% unknown in each race</i>	0.05%	0.82%	8.60%	0.00%	25.77%	0.04%	64.71%	100.00%
<i>% of each race unknown</i>	0.11%	0.13%	1.41%	0.00%	0.65%	0.01%	9.90%	1.60%
Total (number)	20,908	278,641	272,222	1,443	1,771,648	152,791	292,543	2,790,196
% of each race in total	0.75%	9.99%	9.76%	0.05%	63.50%	5.48%	10.48%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	967,503	61,626	139,732	1,168,861
% of total	34.68%	2.21%	5.01%	41.89%
<i>% females in each ethnicity</i>	82.77%	5.27%	11.95%	100.00%
<i>% of each ethnicity females</i>	42.68%	55.73%	33.84%	41.89%
Males (number)	1,283,484	48,930	244,161	1,576,575
% of total	46.00%	1.75%	8.75%	56.50%
<i>% males in each ethnicity</i>	81.41%	3.10%	15.49%	100.00%
<i>% of each ethnicity males</i>	56.62%	44.25%	59.13%	56.50%
Unknown (number)	15,715	23	29,022	44,760
% of total	0.56%	0.00%	1.04%	1.60%
<i>% unknown in each ethnicity</i>	35.11%	0.05%	64.84%	100.00%
<i>% of each ethnicity unknown</i>	0.69%	0.02%	7.03%	1.60%
Total (number)	2,266,702	110,579	412,915	2,790,196
% of each ethnicity in total	81.24%	3.96%	14.80%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 1,335

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	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
Females (number)	118	43	806	59	28,524	3,224	28,852	61,626	395,343
% of total	0.11%	0.04%	0.73%	0.05%	25.80%	2.92%	26.09%	55.73%	14.17%
<i>% females in each race</i>	<i>0.19%</i>	<i>0.07%</i>	<i>1.31%</i>	<i>0.10%</i>	<i>46.29%</i>	<i>5.23%</i>	<i>46.82%</i>	<i>100.00%</i>	<i>33.82%</i>
<i>% of each race females</i>	<i>64.48%</i>	<i>51.19%</i>	<i>21.87%</i>	<i>62.77%</i>	<i>47.33%</i>	<i>51.22%</i>	<i>72.18%</i>	<i>55.73%</i>	<i>47.85%</i>
Males (number)	64	41	2,880	35	31,742	3,054	11,114	48,930	426,633
% of total	0.06%	0.04%	2.60%	0.03%	28.71%	2.76%	10.05%	44.25%	15.29%
<i>% males in each race</i>	<i>0.13%</i>	<i>0.08%</i>	<i>5.89%</i>	<i>0.07%</i>	<i>64.87%</i>	<i>6.24%</i>	<i>22.71%</i>	<i>100.00%</i>	<i>27.06%</i>
<i>% of each race males</i>	<i>34.97%</i>	<i>48.81%</i>	<i>78.13%</i>	<i>37.23%</i>	<i>52.67%</i>	<i>48.52%</i>	<i>27.80%</i>	<i>44.25%</i>	<i>51.64%</i>
Unknown (number)	1	0	0	0	0	16	6	23	4,267
% of total	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.02%	0.15%
<i>% unknown in each race</i>	<i>4.35%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>69.57%</i>	<i>26.09%</i>	<i>100.00%</i>	<i>9.53%</i>
<i>% of each race unknown</i>	<i>0.55%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.25%</i>	<i>0.02%</i>	<i>0.02%</i>	<i>0.52%</i>
Total (number)	183	84	3,686	94	60,266	6,294	39,972	110,579	826,243
% of each race in total	0.17%	0.08%	3.33%	0.09%	54.50%	5.69%	36.15%	100.00%	29.61%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 18C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 392
Females (number)	135	3,548	12,179	4,849	60,009	1,316	82,036	20,711	392
% of total	0.08%	2.20%	7.54%	3.00%	37.16%	0.81%	50.80%	12.83%	
<i>% females in each race</i>	<i>0.16%</i>	<i>4.32%</i>	<i>14.85%</i>	<i>5.91%</i>	<i>73.15%</i>	<i>1.60%</i>	<i>100.00%</i>	<i>25.25%</i>	
<i>% of each race females</i>	<i>48.04%</i>	<i>52.58%</i>	<i>55.47%</i>	<i>53.39%</i>	<i>49.59%</i>	<i>54.86%</i>	<i>50.80%</i>	<i>54.41%</i>	
Males (number)	146	3,200	9,775	4,232	60,987	1,055	79,395	17,353	
% of total	0.09%	1.98%	6.05%	2.62%	37.77%	0.65%	49.17%	10.75%	
<i>% males in each race</i>	<i>0.18%</i>	<i>4.03%</i>	<i>12.31%</i>	<i>5.33%</i>	<i>76.81%</i>	<i>1.33%</i>	<i>100.00%</i>	<i>21.86%</i>	
<i>% of each race males</i>	<i>51.96%</i>	<i>47.42%</i>	<i>44.52%</i>	<i>46.60%</i>	<i>50.40%</i>	<i>43.98%</i>	<i>49.17%</i>	<i>45.59%</i>	
Unknown (number)	0	0	2	1	15	28	46	3	
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.02%	0.03%	0.00%	
<i>% unknown in each race</i>	<i>0.00%</i>	<i>0.00%</i>	<i>4.35%</i>	<i>2.17%</i>	<i>32.61%</i>	<i>60.87%</i>	<i>100.00%</i>	<i>6.52%</i>	
<i>% of each race unknown</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.01%</i>	<i>0.01%</i>	<i>0.01%</i>	<i>1.17%</i>	<i>0.03%</i>	<i>0.01%</i>	
Total (number)	281	6,748	21,956	9,082	121,011	2,399	161,477	38,067	
% of each race in total	0.17%	4.18%	13.60%	5.62%	74.94%	1.49%	100.00%	23.57%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 18A.

Table 19. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis

Table 19A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority by Enrollment
Females (#)	1,343,852	452,629	33.68%
Females (% of total)	43.20%	49.08%	
Males (#)	1,700,018	463,613	27.27%
Males (% of total)	54.65%	50.27%	
Unknown (#)	66,972	5,999	8.96%
Unknown (% of total)	2.15%	0.65%	
TOTAL (#)	3,110,842	922,241	29.65%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 1,770
--

Table 19B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	11,067	181,870	91,854	2,038	780,240	82,887	110,830	1,260,786
% of total	0.38%	6.17%	3.12%	0.07%	26.47%	2.81%	3.76%	42.78%
<i>% females in each race</i>	0.88%	14.43%	7.29%	0.16%	61.89%	6.57%	8.79%	100.00%
<i>% of each race females</i>	47.79%	63.16%	30.30%	53.55%	42.69%	52.00%	32.40%	42.78%
Males (number)	12,060	105,762	205,788	1,767	1,040,096	76,408	177,574	1,619,455
% of total	0.41%	3.59%	6.98%	0.06%	35.29%	2.59%	6.03%	54.95%
<i>% males in each race</i>	0.74%	6.53%	12.71%	0.11%	64.23%	4.72%	10.97%	100.00%
<i>% of each race males</i>	52.08%	36.73%	67.87%	46.43%	56.91%	47.94%	51.91%	54.95%
Unknown (number)	30	300	5,549	1	7,299	94	53,644	66,917
% of total	0.00%	0.01%	0.19%	0.00%	0.25%	0.00%	1.82%	2.27%
<i>% unknown in each race</i>	0.04%	0.45%	8.29%	0.00%	10.91%	0.14%	80.16%	100.00%
<i>% of each race unknown</i>	0.13%	0.10%	1.83%	0.03%	0.40%	0.06%	15.68%	2.27%
Total (number)	23,157	287,932	303,191	3,806	1,827,635	159,389	342,048	2,947,158
% of each race in total	0.79%	9.77%	10.29%	0.13%	62.01%	5.41%	11.61%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	1,028,074	70,601	162,111	1,260,786
% of total	34.88%	2.40%	5.50%	42.78%
<i>% females in each ethnicity</i>	81.54%	5.60%	12.86%	100.00%
<i>% of each ethnicity females</i>	43.63%	57.53%	34.64%	42.78%
Males (number)	1,314,404	52,052	252,999	1,619,455
% of total	44.60%	1.77%	8.58%	54.95%
<i>% males in each ethnicity</i>	81.16%	3.21%	15.62%	100.00%
<i>% of each ethnicity males</i>	55.78%	42.41%	54.07%	54.95%
Unknown (number)	14,036	70	52,811	66,917
% of total	0.48%	0.00%	1.79%	2.27%
<i>% unknown in each ethnicity</i>	20.98%	0.10%	78.92%	100.00%
<i>% of each ethnicity unknown</i>	0.60%	0.06%	11.29%	2.27%
Total (number)	2,356,514	122,723	467,921	2,947,158
% of each ethnicity in total	79.96%	4.16%	15.88%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 1,408

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	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
Females (number)	139	48	1,043	66	31,969	7,315	30,021	70,601	431,706
% of total	0.11%	0.04%	0.85%	0.05%	26.05%	5.96%	24.46%	57.53%	14.65%
<i>% females in each race</i>	<i>0.20%</i>	<i>0.07%</i>	<i>1.48%</i>	<i>0.09%</i>	<i>45.28%</i>	<i>10.36%</i>	<i>42.52%</i>	<i>100.00%</i>	<i>34.24%</i>
<i>% of each race females</i>	<i>64.95%</i>	<i>50.53%</i>	<i>25.51%</i>	<i>64.71%</i>	<i>49.65%</i>	<i>61.76%</i>	<i>71.50%</i>	<i>57.53%</i>	<i>48.84%</i>
Males (number)	74	47	3,042	36	32,408	4,484	11,961	52,052	446,154
% of total	0.06%	0.04%	2.48%	0.03%	26.41%	3.65%	9.75%	42.41%	15.14%
<i>% males in each race</i>	<i>0.14%</i>	<i>0.09%</i>	<i>5.84%</i>	<i>0.07%</i>	<i>62.26%</i>	<i>8.61%</i>	<i>22.98%</i>	<i>100.00%</i>	<i>27.55%</i>
<i>% of each race males</i>	<i>34.58%</i>	<i>49.47%</i>	<i>74.41%</i>	<i>35.29%</i>	<i>50.33%</i>	<i>37.86%</i>	<i>28.49%</i>	<i>42.41%</i>	<i>50.48%</i>
Unknown (number)	1	0	3	0	17	45	4	70	5,995
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.04%	0.00%	0.06%	0.20%
<i>% unknown in each race</i>	<i>1.43%</i>	<i>0.00%</i>	<i>4.29%</i>	<i>0.00%</i>	<i>24.29%</i>	<i>64.29%</i>	<i>5.71%</i>	<i>100.00%</i>	<i>8.96%</i>
<i>% of each race unknown</i>	<i>0.47%</i>	<i>0.00%</i>	<i>0.07%</i>	<i>0.00%</i>	<i>0.03%</i>	<i>0.38%</i>	<i>0.01%</i>	<i>0.06%</i>	<i>0.68%</i>
Total (number)	214	95	4,088	102	64,394	11,844	41,986	122,723	883,855
% of each race in total	0.17%	0.08%	3.33%	0.08%	52.47%	9.65%	34.21%	100.00%	29.99%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 19C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data Reported on Old form: 362
Females (number)	144	3,708	12,443	4,628	60,708	1,435	83,066	20,923	
% of total	0.09%	2.27%	7.60%	2.83%	37.09%	0.88%	50.75%	12.78%	
<i>% females in each race</i>	<i>0.17%</i>	<i>4.46%</i>	<i>14.98%</i>	<i>5.57%</i>	<i>73.08%</i>	<i>1.73%</i>	<i>100.00%</i>	<i>25.19%</i>	
<i>% of each race females</i>	<i>46.75%</i>	<i>53.31%</i>	<i>55.35%</i>	<i>53.55%</i>	<i>49.49%</i>	<i>54.38%</i>	<i>50.75%</i>	<i>54.51%</i>	
Males (number)	164	3,247	10,036	4,012	61,935	1,169	80,563	17,459	
% of total	0.10%	1.98%	6.13%	2.45%	37.84%	0.71%	49.22%	10.67%	
<i>% males in each race</i>	<i>0.20%</i>	<i>4.03%</i>	<i>12.46%</i>	<i>4.98%</i>	<i>76.88%</i>	<i>1.45%</i>	<i>100.00%</i>	<i>21.67%</i>	
<i>% of each race males</i>	<i>53.25%</i>	<i>46.68%</i>	<i>44.64%</i>	<i>46.42%</i>	<i>50.49%</i>	<i>44.30%</i>	<i>49.22%</i>	<i>45.48%</i>	
Unknown (number)	0	1	1	2	16	35	55	4	
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.02%	0.03%	0.00%	
<i>% unknown in each race</i>	<i>0.00%</i>	<i>1.82%</i>	<i>1.82%</i>	<i>3.64%</i>	<i>29.09%</i>	<i>63.64%</i>	<i>100.00%</i>	<i>7.27%</i>	
<i>% of each race unknown</i>	<i>0.00%</i>	<i>0.01%</i>	<i>0.00%</i>	<i>0.02%</i>	<i>0.01%</i>	<i>1.33%</i>	<i>0.03%</i>	<i>0.01%</i>	
Total (number)	308	6,956	22,480	8,642	122,659	2,639	163,684	38,386	
% of each race in total	0.19%	4.25%	13.73%	5.28%	74.94%	1.61%	100.00%	23.45%	
Total (%)	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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 19A.

Table 20. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

Table 20A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority by Sex
Females (#)	11,319	8,402	74.23%
Females (% of total)	68.70%	90.90%	
Males (#)	5,143	828	16.10%
Males (% of total)	31.22%	8.96%	
Unknown (#)	13	13	100.00%
Unknown (% of total)	0.08%	0.14%	
TOTAL (#)	16,475	9,243	56.10%
Total (%)	100%	100.00%	

<p>Total # Protocols with Enrollment Data: 38</p>
--

Table 20B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	129	6	594	0	368	2	9,169	10,268
% of total	0.96%	0.04%	4.42%	0.00%	2.74%	0.01%	68.25%	76.43%
<i>% females in each race</i>	1.26%	0.06%	5.78%	0.00%	3.58%	0.02%	89.30%	100.00%
<i>% of each race females</i>	73.30%	24.00%	60.55%	0.00%	58.60%	50.00%	78.91%	76.43%
Males (number)	47	19	374	1	260	2	2,451	3,154
% of total	0.35%	0.14%	2.78%	0.01%	1.94%	0.01%	18.24%	23.48%
<i>% males in each race</i>	1.49%	0.60%	11.86%	0.03%	8.24%	0.06%	77.71%	100.00%
<i>% of each race males</i>	26.70%	76.00%	38.12%	100.00%	41.40%	50.00%	21.09%	23.48%
Unknown (number)	0	0	13	0	0	0	0	13
% of total	0.00%	0.00%	0.10%	0.00%	0.00%	0.00%	0.00%	0.10%
<i>% unknown in each race</i>	0.00%	0.00%	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%
<i>% of each race unknown</i>	0.00%	0.00%	1.33%	0.00%	0.00%	0.00%	0.00%	0.10%
Total (number)	176	25	981	1	628	4	11,620	13,435
% of each race in total	1.31%	0.19%	7.30%	0.01%	4.67%	0.03%	86.49%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	1,282	7,553	1,433	10,268
% of total	9.54%	56.22%	10.67%	76.43%
<i>% females in each ethnicity</i>	12.49%	73.56%	13.96%	100.00%
<i>% of each ethnicity females</i>	48.63%	98.27%	46.03%	76.43%
Males (number)	1,341	133	1,680	3,154
% of total	9.98%	0.99%	12.50%	23.48%
<i>% males in each ethnicity</i>	42.52%	4.22%	53.27%	100.00%
<i>% of each ethnicity males</i>	50.87%	1.73%	53.97%	23.48%
Unknown (number)	13	0	0	13
% of total	0.10%	0.00%	0.00%	0.10%
<i>% unknown in each ethnicity</i>	100.00%	0.00%	0.00%	100.00%
<i>% of each ethnicity unknown</i>	0.49%	0.00%	0.00%	0.10%
Total (number)	2,636	7,686	3,113	13,435
% of each ethnicity in total	19.62%	57.21%	23.17%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

<p>Number of Protocols with Enrollment Data Reported on New Form: 27</p>

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	1	0	0	0	2	0	7,550	7,553
% of total	0.01%	0.00%	0.00%	0.00%	0.03%	0.00%	98.23%	98.27%
<i>% females in each race</i>	<i>0.01%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.03%</i>	<i>0.00%</i>	<i>99.96%</i>	<i>100.00%</i>
<i>% of each race females</i>	<i>100.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>66.67%</i>	<i>0.00%</i>	<i>98.28%</i>	<i>98.27%</i>
Males (number)	0	0	0	0	1	0	132	133
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	1.72%	1.73%
<i>% males in each race</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.75%</i>	<i>0.00%</i>	<i>99.25%</i>	<i>100.00%</i>
<i>% of each race males</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>33.33%</i>	<i>0.00%</i>	<i>1.72%</i>	<i>1.73%</i>
Unknown (number)	0	0	0	0	0	0	0	0
% of total	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
<i>% unknown in each race</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
<i>% of each race unknown</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
Total (number)	1	0	0	0	3	0	7,682	7,686
% of each race in total	0.01%	0.00%	0.00%	0.00%	0.04%	0.00%	99.95%	100.00%
Total (%)	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%

Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
8,283
61.65%
80.67%
93.36%
576
4.29%
18.26%
6.49%
13
0.10%
100.00%
0.15%
8,872
66.04%
100.00%

Table 20C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Females (number)	1	20	69	29	922	10	1,051	119
% of total	0.03%	0.66%	2.27%	0.95%	30.33%	0.33%	34.57%	3.91%
<i>% females in each race</i>	<i>0.10%</i>	<i>1.90%</i>	<i>6.57%</i>	<i>2.76%</i>	<i>87.73%</i>	<i>0.95%</i>	<i>100.00%</i>	<i>11.32%</i>
<i>% of each race females</i>	<i>25.00%</i>	<i>32.26%</i>	<i>30.53%</i>	<i>36.71%</i>	<i>34.86%</i>	<i>41.67%</i>	<i>34.57%</i>	<i>32.08%</i>
Males (number)	3	42	157	50	1,723	14	1,989	252
% of total	0.10%	1.38%	5.16%	1.64%	56.68%	0.46%	65.43%	8.29%
<i>% males in each race</i>	<i>0.15%</i>	<i>2.11%</i>	<i>7.89%</i>	<i>2.51%</i>	<i>86.63%</i>	<i>0.70%</i>	<i>100.00%</i>	<i>12.67%</i>
<i>% of each race males</i>	<i>75.00%</i>	<i>67.74%</i>	<i>69.47%</i>	<i>63.29%</i>	<i>65.14%</i>	<i>58.33%</i>	<i>65.43%</i>	<i>67.92%</i>
Unknown (number)	0	0	0	0	0	0	0	0
% of total	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
<i>% unknown in each race</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>
<i>% of each race unknown</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
Total (number)	4	62	226	79	2,645	24	3,040	371
% of each race in total	0.13%	2.04%	7.43%	2.60%	87.01%	0.79%	100.00%	12.20%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on Old form: 11
--

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)

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

Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 20A.

Table 21. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2009 and Reported in FY2010: Percent Analysis

Table 21A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	% Minority Enrollment
Females (#)	16,128	10,426	64.65%
Females (% of total)	79.19%	93.07%	
Males (#)	4,226	763	18.05%
Males (% of total)	20.75%	6.81%	
Unknown (#)	13	13	100.00%
Unknown (% of total)	0.06%	0.12%	
TOTAL (#)	20,367	11,202	55.00%
Total (%)	100%	100.00%	

Total # Protocols with Enrollment Data: 46

Table 21B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

I. Total of All Subjects by Race

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	237	177	2,178	0	3,599	3	8,879	15,073
% of total	1.37%	1.02%	12.58%	0.00%	20.79%	0.02%	51.30%	87.09%
<i>% females in each race</i>	1.57%	1.17%	14.45%	0.00%	23.88%	0.02%	58.91%	100.00%
<i>% of each race females</i>	83.45%	88.94%	84.95%	0.00%	93.34%	60.00%	85.38%	87.09%
Males (number)	47	22	373	1	257	2	1,520	2,222
% of total	0.27%	0.13%	2.16%	0.01%	1.48%	0.01%	8.78%	12.84%
<i>% males in each race</i>	2.12%	0.99%	16.79%	0.05%	11.57%	0.09%	68.41%	100.00%
<i>% of each race males</i>	16.55%	11.06%	14.55%	100.00%	6.66%	40.00%	14.62%	12.84%
Unknown (number)	0	0	13	0	0	0	0	13
% of total	0.00%	0.00%	0.08%	0.00%	0.00%	0.00%	0.00%	0.08%
<i>% unknown in each race</i>	0.00%	0.00%	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%
<i>% of each race unknown</i>	0.00%	0.00%	0.51%	0.00%	0.00%	0.00%	0.00%	0.08%
Total (number)	284	199	2,564	1	3,856	5	10,399	17,308
% of each race in total	1.64%	1.15%	14.81%	0.01%	22.28%	0.03%	60.08%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

II. Total of All Subjects by Ethnicity

Sex/ Gender	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Females (number)	6,000	7,712	1,361	15,073
% of total	34.67%	44.56%	7.86%	87.09%
<i>% females in each ethnicity</i>	39.81%	51.16%	9.03%	100.00%
<i>% of each ethnicity females</i>	89.45%	99.18%	48.19%	87.09%
Males (number)	695	64	1,463	2,222
% of total	4.02%	0.37%	8.45%	12.84%
<i>% males in each ethnicity</i>	31.28%	2.88%	65.84%	100.00%
<i>% of each ethnicity males</i>	10.36%	0.82%	51.81%	12.84%
Unknown (number)	13	0	0	13
% of total	0.08%	0.00%	0.00%	0.08%
<i>% unknown in each ethnicity</i>	100.00%	0.00%	0.00%	100.00%
<i>% of each ethnicity unknown</i>	0.19%	0.00%	0.00%	0.08%
Total (number)	6,708	7,776	2,824	17,308
% of each ethnicity in total	38.76%	44.93%	16.32%	100.00%
Total (%)	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on New Form: 35
--

**III. New Form (Part B): Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date
Total of All Hispanic or Latino Subjects by Race**

Sex/ Gender	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian / Pacific Islander	White	More Than One Race	Unknown/ Other	Total
Females (number)	1	0	0	0	190	0	7,521	7,712
% of total	0.01%	0.00%	0.00%	0.00%	2.44%	0.00%	96.72%	99.18%
<i>% females in each race</i>	<i>0.01%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>2.46%</i>	<i>0.00%</i>	<i>97.52%</i>	<i>100.00%</i>
<i>% of each race females</i>	100.00%	0.00%	0.00%	0.00%	99.48%	0.00%	99.17%	99.18%
Males (number)	0	0	0	0	1	0	63	64
% of total	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.81%	0.82%
<i>% males in each race</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>1.56%</i>	<i>0.00%</i>	<i>98.44%</i>	<i>100.00%</i>
<i>% of each race males</i>	0.00%	0.00%	0.00%	0.00%	0.52%	0.00%	0.83%	0.82%
Unknown (number)	0	0	0	0	0	0	0	0
% of total	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
<i>% unknown in each race</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
<i>% of each race unknown</i>	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total (number)	1	0	0	0	191	0	7,584	7,776
% of each race in total	0.01%	0.00%	0.00%	0.00%	2.46%	0.00%	97.53%	100.00%
Total (%)	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%

Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
10,306
59.54%
68.37%
95.18%
509
2.94%
22.91%
4.70%
13
0.08%
100.00%
0.12%
10,828
62.56%
100.00%

Table 21C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Sex/ Gender	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Females (number)	1	21	70	28	926	9	1,055	120
% of total	0.03%	0.69%	2.29%	0.92%	30.27%	0.29%	34.49%	3.92%
<i>% females in each race</i>	<i>0.09%</i>	<i>1.99%</i>	<i>6.64%</i>	<i>2.65%</i>	<i>87.77%</i>	<i>0.85%</i>	<i>100.00%</i>	<i>11.37%</i>
<i>% of each race females</i>	20.00%	33.33%	30.43%	36.84%	34.79%	39.13%	34.49%	32.09%
Males (number)	4	42	160	48	1,736	14	2,004	254
% of total	0.13%	1.37%	5.23%	1.57%	56.75%	0.46%	65.51%	8.30%
<i>% males in each race</i>	<i>0.20%</i>	<i>2.10%</i>	<i>7.98%</i>	<i>2.40%</i>	<i>86.63%</i>	<i>0.70%</i>	<i>100.00%</i>	<i>12.67%</i>
<i>% of each race males</i>	80.00%	66.67%	69.57%	63.16%	65.21%	60.87%	65.51%	67.91%
Unknown (number)	0	0	0	0	0	0	0	0
% of total	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
<i>% unknown in each race</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>
<i>% of each race unknown</i>	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total (number)	5	63	230	76	2,662	23	3,059	374
% of each race in total	0.16%	2.06%	7.52%	2.48%	87.02%	0.75%	100.00%	12.23%
Total (%)	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data Reported on Old form: 11
--

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)
Plain Typeface: Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)
Columns denoted with shading (American Indian/ Alaska Native, Asian, Black/ African American, Hawaiian/ Pacific Islander, Asian/ Pacific Islander, Hispanic and Unknown, More than one race and Unknown/Other) are summed to calculate Minority enrollment in Table 21A.

Table 22. NIH Sixteen-Year Trends for Protocol and Enrollment Data: 1995-2010*

Table 22A Part I. Sixteen-Year Increases in Protocols and Enrollment Data

FY Reported	1995	2010	Relative Increase, 2010 / 1995
Total Protocols with Enrollment	3,188	12,079	3.8
Total Enrollment	1,021,493	23,363,635	22.9
Total Minorities	374,433	7,510,763	20.1
% Minorities	36.7%	32.1%	0.9

Table 22A Part II. Nine-Year Increases in Protocols and Enrollment Data: Foreign and Domestic

FY Reported	2002	2010	Relative Increase, 2010 / 2002
Total DOMESTIC Enrollment	10,192,401	21,523,076	2.1
Total FOREIGN Enrollment	946,083	1,840,559	1.9

*NOTE: 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 22B. Sixteen-Year Summary of Total Number of Protocols Reported: FY 1995-2010

FY Reported/ FY Funded	Protocol Form*	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
1995/1994	Old	3,188			
1996/1995	Old	6,036			
1997/1996	Old	5,692			
1998/1997	Old	7,602			
1999/1998	Old	8,285			
2000/1999	Old	9,390			
2001/2000	Old	10,212			
2002/2001	Old + New	8,945	8,463	482	94.6%
2003/2002	Old + New	10,216	9,578	638	93.8%
2004/2003	Old + New	10,125	9,760	365	96.4%
2005/2004	Old + New	10,233	9,862	371	96.4%
2006/2005	Old + New	10,758	10,294	464	95.7%
2007/2006	Old + New	10,914	10,463	451	95.9%
2008/2007	Old + New	11,045	10,548	497	95.5%
2009/2008	Old + New	11,171	10,263	908	91.9%
2010/2009	Old + New	12,079	11,189	890	92.6%

Figure 22a. Total Protocols by Year Reported

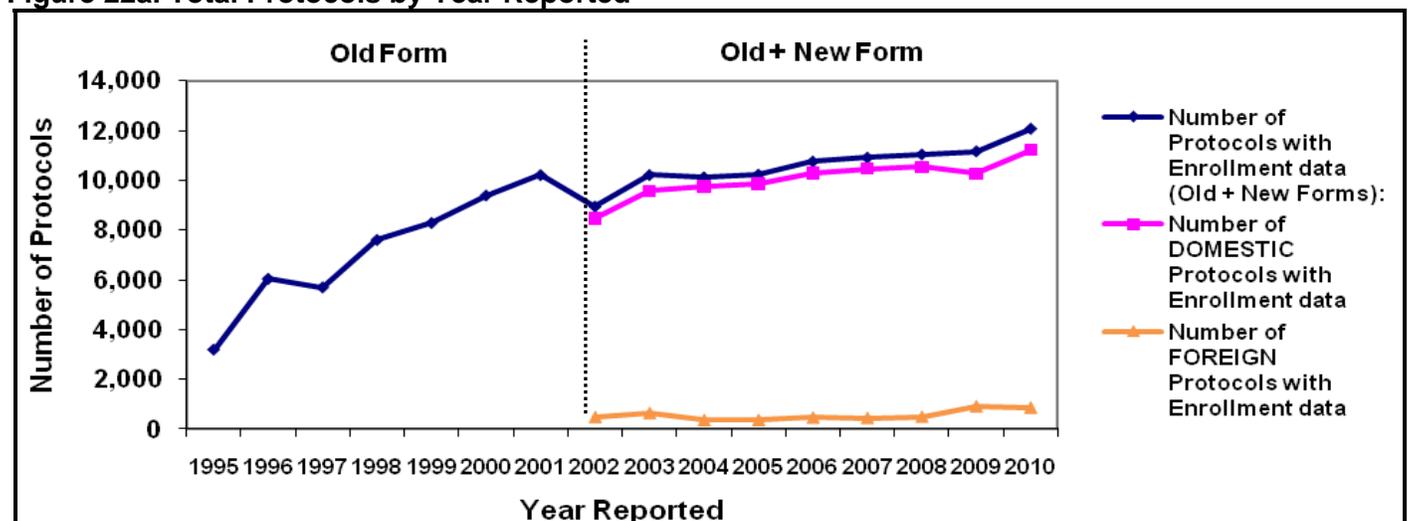


Table 22C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2010

FY Reported/ FY Funded	Total Enrollment (Old + New Forms)	Total DOMESTIC Enrollment	Percent DOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGN Enrollment
2002/2001	11,138,484	10,192,401	91.5%	946,083	8.5%
2003/2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%
2004/2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%
2005/2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%
2006/2005	14,830,930	11,425,701	77.0%	3,405,229	23.0%
2007/2006	17,448,458	16,180,588	92.7%	1,267,870	7.3%
2008/2007	15,412,355	14,134,627	91.7%	1,277,728	8.3%
2009/2008	19,138,738	17,848,074	93.3%	1,290,664	6.7%
2010/2009	23,363,635	21,523,076	92.1%	1,840,559	7.9%

Figure 22b. Relative Proportions of Domestic and Foreign Enrollment

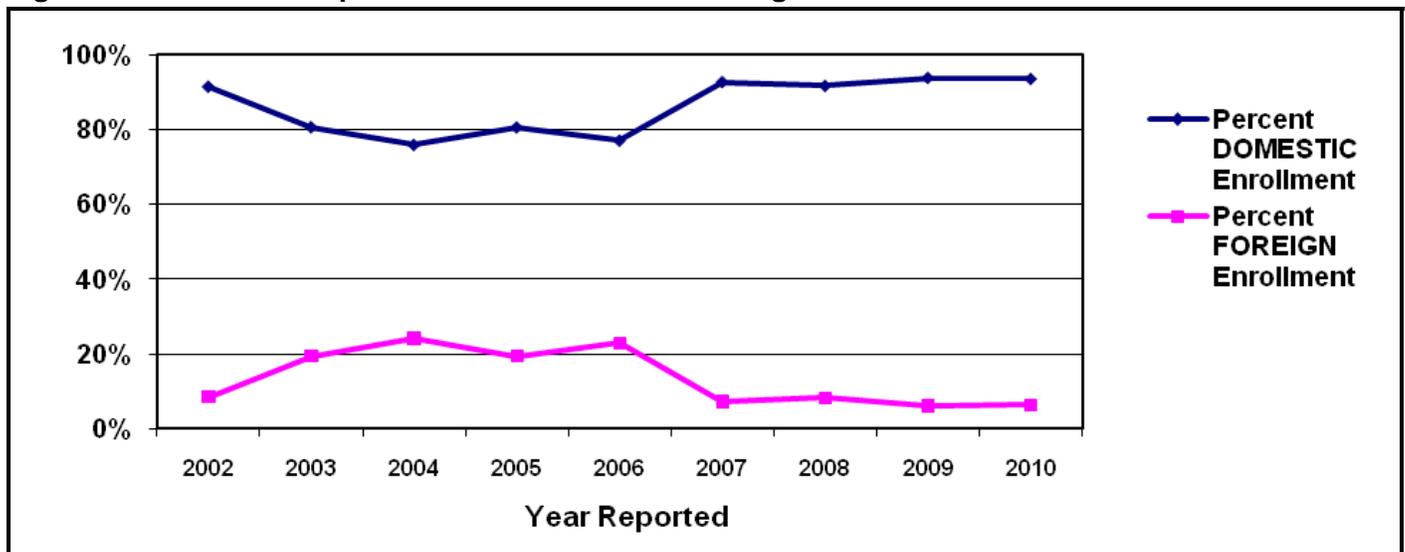


Table 23. NIH Sixteen-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2010

Table 23A. SIXTEEN-YEAR SUMMARY TOTALS: Enrollment By Sex/Gender and Minority Categories in All Protocols (Old + New Forms)

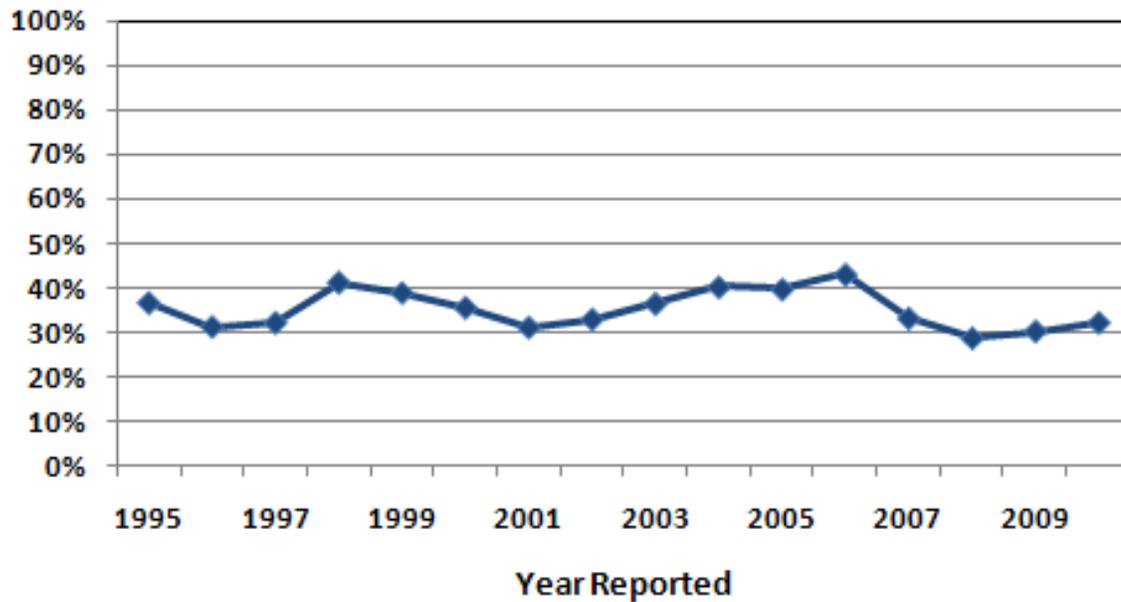
FY Reported/ FY Funded	Form	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms)
1995/1994	Old	528,421	459,921	33,151	1,021,493	374,433	3,188
% Reported in 1995		51.7%	45.0%	3.2%	100.0%	36.7%	
1996/1995	Old	4,130,385	2,583,865	91,054	6,805,304	2,125,958	6,036
% Reported in 1996		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
% Reported in 1997		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
% Reported in 1998		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
% Reported in 1999		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
% Reported in 2000		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
% Reported in 2001		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
% Reported in 2002		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
% Reported in 2003		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
% Reported in 2004		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
% Reported in 2005		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
% Reported in 2006		63.9%	34.9%	1.25%	100.0%	43.1%	
2007/2006	Old + New	10,152,590	6,887,793	408,075	17,448,458	5,783,543	10,914
% Reported in 2007		58.2%	39.5%	2.34%	100.0%	33.1%	
2008/2007	Old + New	9,243,966	5,991,739	176,650	15,412,355	4,412,106	11,045
% Reported in 2008		60.0%	38.9%	1.15%	100.0%	28.6%	
2009/2008	Old + New	11,439,143	7,570,646	128,949	19,138,738	5,783,543	11,171
% Reported in 2009		59.8%	39.6%	0.67%	100.0%	30.2%	
2010/2009	Old + New	13,102,832	10,044,444	216,359	23,363,635	7,510,763	12,079
% Reported in 2010		56.1%	43.0%	0.9%	100.0%	32.1%	

Table 23A Comments:

- Table 23A summarizes enrollment by sex/gender and minority race/ethnicity categories for the sixteen-year reporting period (1995-2010). The data are compiled from Tables 23B, 23C and 23D 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 23C and 23D).
- 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).

Figure 23a. NIH Sixteen-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2010

Minority Enrollment Clinical Research by Year Reported



Male and Female Enrollment Clinical Research by Year Reported

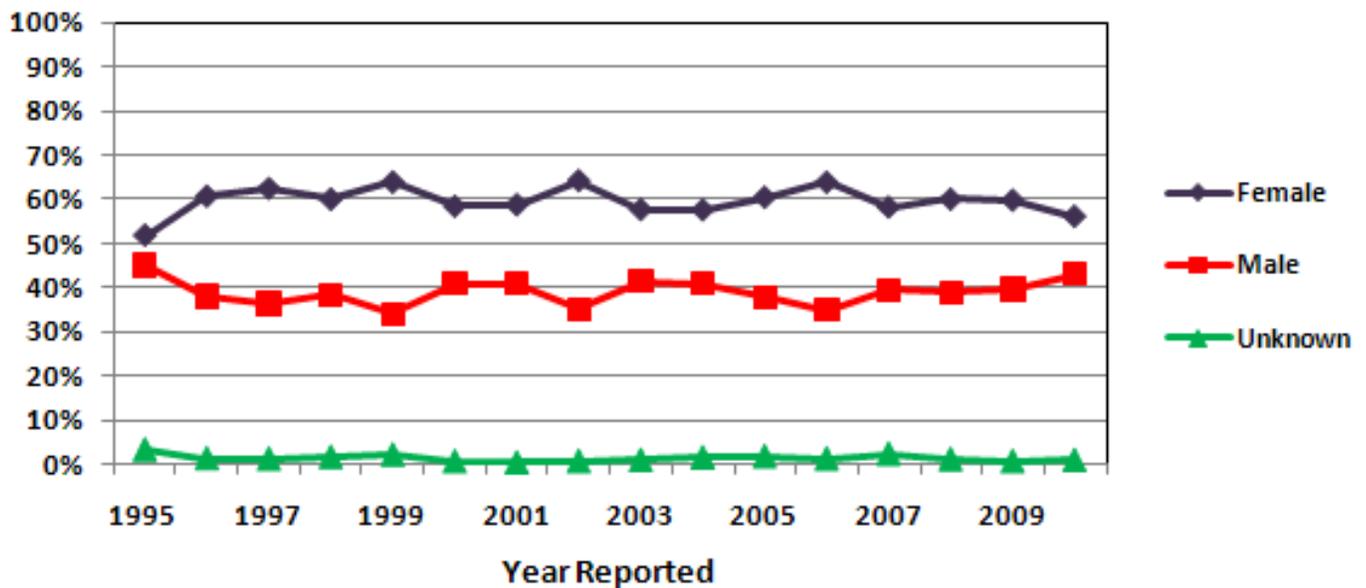


Table 23 (cont'd): NIH Sixteen-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY1995-2010

Notes: Tables 23B-D

NOTE 1: The shaded portions of the Tables 23B, 23C and 23D 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 23B, 23C and 23D are combined to provide the summary data in Table 23A.

Table 23B. 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
% Reported in 1995	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
% Reported in 1996	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
% Reported in 1997	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
% Reported in 1998	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
% Reported in 1999	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
% Reported in 2000	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
% Reported in 2001	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
% Reported in 2002	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
% Reported in 2003	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
% Reported in 2004	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
% Reported in 2005	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
% Reported in 2006	1.5%	9.9%	11.2%	5.9%	66.6%	4.8%	100.0%	28.6%	
2007/2006	5,372	51,742	238,004	83,192	1,097,387	48,630	1,524,327	378,310	1,098
% Reported in 2007	0.4%	3.4%	15.6%	5.5%	72.0%	3.2%	100.0%	24.8%	
2008/2007	1,930	16,258	99,164	28,819	460,533	19,715	626,419	146,171	915
% Reported in 2008	0.3%	2.6%	15.8%	4.6%	73.5%	3.1%	100.0%	23.3%	
2009/2008	1,213	11,652	42,405	19,301	299,115	15,780	389,466	74,571	843
% Reported in 2009	0.3%	3.0%	10.9%	5.0%	76.8%	4.1%	100.0%	19.1%	
2010/2009	682	9,081	32,551	15,441	203,303	5,699	266,757	57,755	532
% Reported in 2010	0.3%	3.4%	12.2%	5.8%	76.2%	2.1%	100.0%	21.7%	

Table 23 (cont'd): NIH Nine-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2007: Enrollment by Race and Ethnicity

Orientation to Tables 23C and 23D

1. The New Form consists of Parts A and B (Tables 6C and 6D) for reporting years 2002-2010. This Form is provided as part of the annual progress report.
2. Table 23C displays the New Form Part A for reporting separate race and ethnicity data.
3. Table 23D 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.

23C. New Form Part A: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats

I. Total of All Subjects by Race

FY Reported/ FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total*
2002/2001	77,734	354,049	547,776	21,636	2,651,541	30,955	720,362	4,404,053
% Reported in 2002	1.8%	8.0%	12.4%	0.5%	60.2%	0.7%	16.4%	100.0%
2003/2002	63,544	2,138,002	960,090	37,569	5,415,710	99,462	1,012,622	9,726,999
% Reported in 2003	0.7%	22.0%	9.9%	0.4%	55.7%	1.0%	10.4%	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
% Reported in 2004	0.6%	28.0%	8.9%	0.4%	52.0%	1.2%	8.9%	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
% Reported in 2005	2.1%	22.2%	9.9%	0.4%	56.0%	1.3%	8.1%	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
% Reported in 2006	1.0%	25.6%	9.3%	0.3%	52.5%	2.4%	8.9%	100.0%
2007/2006	145,417	1,356,900	2,012,695	57,149	10,341,483	278,068	1,732,419	15,924,131
% Reported in 2007	0.9%	8.5%	12.6%	0.4%	64.9%	1.7%	10.9%	100.0%
2008/2007	134,494	1,168,053	1,835,035	48,560	9,651,267	181,941	1,766,586	14,785,936
% Reported in 2008	0.9%	7.9%	12.4%	0.3%	65.3%	1.2%	11.9%	100.0%
2009/2008	154,515	1,840,539	2,287,577	50,339	12,790,945	323,839	1,301,518	18,749,272
% Reported in 2009	0.8%	9.8%	12.2%	0.3%	68.2%	1.7%	6.9%	100.0%
2010/2009	361,229	2,133,596	2,949,614	150,856	15,278,117	358,946	1,864,520	23,096,878
% Reported in 2010	1.6%	9.2%	12.8%	0.7%	66.1%	1.6%	8.1%	100.0%

II. Total of All Subjects by Ethnicity

FY Reported/ FY Funded	Not Hispanic	Hispanic or Latino**	Unknown/ Not Reported	Total*
2002/2001	3,071,952	292,429	1,039,672	4,404,053
% Reported in 2002	69.8%	6.6%	23.6%	100.0%
2003/2002	8,162,259	611,641	953,099	9,726,999
% Reported in 2003	83.9%	6.3%	9.8%	100.0%
2004/2003	13,168,842	756,339	1,585,131	15,510,312
% Reported in 2004	84.9%	4.9%	10.2%	100.0%
2005/2004	11,804,164	773,939	1,133,595	13,711,698
% Reported in 2005	86.1%	5.6%	8.3%	100.0%
2006/2005	11,308,244	1,054,313	1,143,123	13,505,680
% Reported in 2006	83.7%	7.8%	8.5%	100.0%
2007/2006	13,017,124	1,169,092	1,737,915	15,924,131
% Reported in 2007	81.7%	7.3%	10.9%	100.0%
2008/2007	11,881,644	1,116,699	1,787,594	14,785,937
% Reported in 2008	80.4%	7.6%	12.1%	100.0%
2009/2008	16,033,547	1,302,944	1,412,781	18,749,272
% Reported in 2009	85.5%	6.9%	7.5%	100.0%
2010/2009	18,962,836	1,958,060	2,175,982	23,096,878
% Reported in 2010	82.1%	8.5%	9.4%	100.0%

* These totals must agree

** The Hispanic enrollment totals must agree with totals in Table 23D.

Table 23 (cont'd): NIH Nine-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2007: Enrollment by Race and Ethnicity

Table 23D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported/ FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total Hispanic or Latino**	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Protocols with Enrollment data (New Form)
2002/2001	4,867	1,305	13,066	101	159,252	7,390	106,448	292,429	1297850	2,758
% Reported in 2002	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	3859622	5,313
% Reported in 2003	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	6718662	7,343
% Reported in 2004	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	5603876	8,447
% Reported in 2005	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	6009338	9,367
% Reported in 2006	4.3%	0.6%	2.1%	0.2%	39.6%	17.6%	35.6%	100.0%	44.5%	
2007/2006	37,581	7,414	31,239	4,310	538,216	100,197	450,135	1,169,092	4356434	9,816
% Reported in 2007	3.2%	0.6%	2.7%	0.4%	46.0%	8.6%	38.5%	100.0%	29.5%	
2008/2007	34,335	31,616	85,548	2,369	518,825	64,979	379,027	1,116,699	4265935	10,130
% Reported in 2008	3.1%	2.8%	7.7%	0.2%	46.5%	5.8%	33.9%	100.0%	28.9%	
2009/2008	39,198	53,546	91,184	3,103	729,355	63,934	322,808	1,303,128	5708972	10,328
% Reported in 2009	3.0%	4.1%	7.0%	0.2%	56.0%	4.9%	24.8%	100.0%	30.4%	
2010/2009	203,106	9,836	170,553	2,824	1,015,859	72,974	482,908	1,958,060	7,453,008	11,547
% Reported in 2010	10.4%	0.5%	8.7%	0.1%	51.9%	3.7%	24.7%	100.0%	32.3%	

** These totals must agree with the Hispanic enrollment in Table 23C.11

Table 23 (cont'd): NIH Nine-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2007: Enrollment by Race and Ethnicity

Table 23E. Comparison of Domestic and Foreign Enrollment & Protocols with Total Enrollment for the period FY2002-2010

FY Reported/ Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC Enrollment	Percent DOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGN Enrollment	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols	Percent Domestic Protocols	Number of FOREIGN Protocols	Percent Foreign Protocols
2002/2001	11,138,484	10,192,401	91.5%	946,083	8.5%	8,945	8,463	94.6%	482	5.4%
2003/2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%	10,216	9,578	93.8%	638	6.2%
2004/2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%	10,125	9,760	96.4%	365	3.6%
2005/2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%	10,233	9,862	96.4%	371	3.6%
2006/2005	14,830,930	11,425,701	77.0%	3,405,229	23.0%	10,758	10,294	95.7%	464	4.3%
2007/2006	17,448,458	16,180,588	92.7%	1,267,870	7.3%	10,914	10,463	95.9%	451	4.1%
2008/2007	15,412,355	14,134,627	91.7%	1,277,728	8.3%	11,045	10,548	95.5%	497	4.5%
2009/2008	19,138,738	17,848,074	93.3%	1,290,664	6.7%	11,171	10,263	91.9%	908	8.1%
2010/2009	23,363,635	21,523,076	92.1%	1,840,559	7.9%	12,079	11,189	92.6%	890	7.4%

Table 23E comments:

1. The Total Enrollment, Total Domestic and Total Foreign Enrollment increased overall from FY 2002 – 2010.
2. The Percent Domestic enrollment decreased from over 90% reported in FY2002 to less than 80% reported in FY2010. Percent Foreign enrollment has correspondingly increased during the same period.

Figure 23b. NIH Nine-Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research

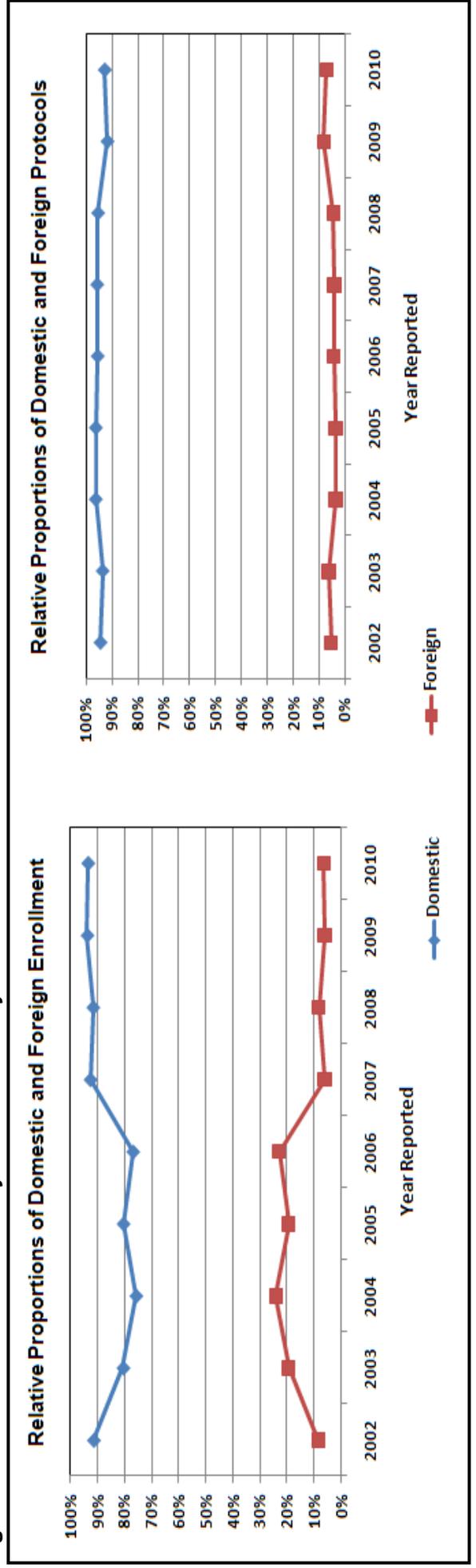


Table 23F. Comparison of Domestic and Foreign Minority Participation for FY 2002-2010

FY Reported/ FY Funded	FOREIGN Minority Enrollment	FOREIGN Total Enrollment	DOMESTIC Minority Enrollment	DOMESTIC Total Enrollment
2002/2001	777,461	946,083	2,754,820	10,149,869
% Reported in 2002	82.2%	100.0%	27.1%	100.0%
2003/2002	2,452,329	2,860,897	2,935,363	11,911,357
% Reported in 2003	85.7%	100.0%	24.6%	100.0%
2004/2003	4,147,255	4,564,127	3,464,356	14,359,793
% Reported in 2004	90.9%	100.0%	24.1%	100.0%
2005/2004	2,776,565	3,052,894	3,468,864	12,669,858
% Reported in 2005	90.9%	100.0%	27.4%	100.0%
2006/2005	3,087,181	3,405,229	3,301,135	11,425,701
% Reported in 2006	90.7%	100.0%	28.9%	100.0%
2007/2006	932,686	1,267,870	4,283,738	16,180,588
% Reported in 2007	73.6%	100.0%	26.5%	100.0%
2008/2007	864,945	1,277,728	3,521,691	14,134,627
% Reported in 2008	67.7%	100.0%	24.9%	100.0%
2009/2008	899,749	1,290,664	4,883,794	17,848,074
% Reported in 2009	69.7%	100.0%	27.4%	100.0%
2010/2009	1,469,232	1,840,559	6,041,531	21,523,076
% Reported in 2010	79.8%	100.0%	28.1%	100.0%

Table 23F Comments:

1. In FY 2002, a single, large, foreign research study (R01TW005993) entitled “Monitoring tobacco mortality in 2M adults in 4 countries” expanded enrollment to over 1.5 million participants, causing a sharp increase in foreign minority enrollment reported in FY 2003.
2. In FY 2003, a single, large, foreign research study (R01TW005991) entitled “Strengthening monitoring of Indian tobacco mortality” expanded enrollment to over 2 million participants, causing a sharp increase in foreign minority enrollment reported in FY 2003.

Figure 23c. Comparison of Domestic and Foreign Minority Participation for FY 2002-2010

