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 2008 and Fiscal Year 2009

2010 Report

Table of Contents

Appendices

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 1985[1], the NIH established a policy in 1986 for the inclusion of women in clinical research. This policy, which ***urged*** the inclusion of women, was first published in the NIH Guide to Grants and Contracts in 1987[2]. 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 of the revised guidelines across the NIH were developed through the establishment and deliberations of an NIH Tracking and Inclusion Committee made up of representatives of the directors of each of the Institutes and Centers (ICs). This trans-NIH committee, convened by the Office of Research on Women's Health (ORWH) and co-chaired with a senior IC official, meets on a regular basis, focusing on consistent and widespread adherence to the NIH guidelines by all the ICs. Working in collaboration with the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and other components of NIH, ORWH coordinates the activity of developing and establishing data collection and reporting methodologies to ensure uniform standards and definitions in the reporting of data on women and minority participants in NIH-funded clinical research.

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

GAO Report, May 2000: Recommendations and Actions Taken

Following a Congressional request for an assessment of NIH progress in implementing the1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled *Women's Health - NIH Has Increased Its Efforts to Include Women in Research.*[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 the NIH staff who transmit data to the inclusion tracking data system receive ongoing training on the requirements and purpose of the system.

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

- **Updating the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research**[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, while the number of studies using the 1977 format (OLD FORM) has steadily decreased as the studies funded prior to FY2002 are completed.

The 1997 OMB reporting format (NEW FORM) and standards 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.

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

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

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

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

Continuing Implementation and Monitoring Activities

In FY2007, two training sessions were collaboratively developed and then sponsored through OER for NIH staff involved in the management or review of clinical research studies. The half-day training sessions were held and were also webcast throughout the NIH community. While some staff participated in the training via the web, approximately 300 NIH staff attended each session in person. Participants received a certificate of completion and, if appropriate, extramural scientist administrator (ESA) credits after completing a short test. The training subcommittee of the NIH Tracking and Inclusion Committee continually updates training documents and methods of training for NIH staff.

The PHS 398 Grant Application was significantly revised to provide additional instructions concerning the Women and Minorities Inclusion Policy and the revised 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.

Communication and Outreach Efforts to the Scientific Community

NIH staff 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

As a way of monitoring compliance with the policy, aggregate data tables compiled from each NIH Institute and Center are provided in this chapter. Because the data included in the tables are aggregate data from across NIH, the data tables provide 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 not to satisfy any quotas for proportional representation based upon census data, but rather to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will be generalizable to the entire population of the United States. The 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 for a particular study. The Scientific Review Group (SRG) determines if the implementation plan for an application is unacceptable if it: 1) fails to provide sufficient information about target enrollment; 2) does not adequately justify limited or lack of inclusion of women or minorities; or 3) does not realistically address recruitment and retention. For NIH-defined Phase III clinical trials, the SRG also evaluates the description of plans to conduct analyses, as appropriate, to address differences in the intervention effect by sex/gender and/or racial/ethnic groups. Applications with unacceptable inclusion plans cannot be funded until NIH staff is assured that revised inclusion plans from the investigators meet the inclusion policy requirements. Research awards covered by this policy require the grantee to report annually on enrollment of women and men, and on the race and ethnicity of research participants so that enrollment can be monitored.

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

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

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

Office of Research on Women's Health Website: HYPERLINK "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 FY2008 and FY2009

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

Analysis of aggregate NIH data on inclusion for FY2008 and FY2009 documents participants of all ages, that substantial numbers of women and men, non-minority men, and minorities of all ages have been included as research subjects in NIH clinical trials and other human subject research studies during these fiscal years. However, caution should be utilized to avoid over-interpreting the figures that are provided.

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 2008 and 2009

In FY2008 there were 15,598 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 11,045 protocols reported human subject participation as noted in this report's trend summary tables (table 1A). Of these, 95.5% were domestic protocols and 4.5% were foreign protocols (table 1A). Approximately 15.4 million participants were enrolled in extramural and intramural research protocols of which 91.7% were domestic participants and 8.3% were foreign participants (table 1B). Of the 15.4 million participants, 60.0% were women, 38.9% were men and 1.1% did not provide sex identification (table 1B). Further, 28.5% of the total participants, and 24.9% of the Domestic-only participants, were reported as minorities following the current OMB categories for race and ethnicity (table 1C).

Correspondingly, 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 (table 2A). Of these, 91.9% were domestic protocols and 8.1% were foreign protocols (table 2A). Approximately 19.1 million participants were enrolled in extramural and intramural research protocols of which 93.9% were domestic participants and 6.1% were foreign participants (table 2B). Of the 19.1 million participants, 59.8% were women, 39.6% were men and 0.7% did not provide sex identification (table 2B). Further 30.2% of the total participants, and 27.8% of the Domestic-protocol participants, were reported as minorities following the current OMB categories for race and ethnicity (table 2C).

Although the number of participants in all extramural and intramural clinical research increased (15.4M in FY2008 and 19.1M in FY2009), there was no significant change in the proportion of women and men (60.0%F and 38.9%M in FY2008; and 59.8%F and 39.6%M in FY2009).

NIH Defined Phase III Clinical Research: FY2008 and FY2009

In FY2008 there were 726 extramural and intramural Phase III clinical research protocols, of which 639 protocols reported human subject participation (table 3A). Of these, 91.5% were domestic protocols and 8.5% were foreign protocols (table 3A). Clinical studies not included in this analysis are those studies that have just begun and have not reported enrollment data or have not begun recruiting patients. A total of 792,578 participants were enrolled in extramural and intramural Phase III research protocols of which 74.6% were domestic participants and 25.4% were foreign participants (table 3B). Of the 792,578 participants, 57.5% were women, 40.3% were men and 2.2% did not provide sex identification (table 3B). Further 38.9% of the total participants, and 20.2% of Domestic-protocol participants, in Phase III clinical research were reported as minorities following the current OMB categories for race and ethnicity (table 3C).

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

Moreover, in FY 2008, there were 475 extramural and intramural Phase III research protocols reporting data following the current OMB standards for reporting by both race and ethnicity (table 4D). Accordingly, minority representation by race was highest for Blacks at 18.4% and lowest for Hawaiian/Pacific Islanders 0.1%. Asians represented 17.0%, American Indian/Alaska Natives 2.7% and Whites 50.2% of participants (table 4C). Participants identifying as *More Than One* Race were 2.2% of the total number of participants (table 4C). In addition, 9.4% did not identify a race category (table 4C). Of the 475 extramural and intramural Phase III research protocols designating an ethnicity in FY2008, 82.3 % of total participants identified as “Not Hispanic”, 11.5 % of the total participants identified as “Hispanic or Latino”, and 6.2% of the total participants did not identify an ethnicity category (table 4C). The racial distribution of the “Hispanic or Latino” participants is also provided separately (table 4D).

Correspondingly, in FY2009 there were 662 extramural and intramural Phase III clinical research protocols, of which 630 protocols reported human subject participation (table 5A). Of these, 72.5% were domestic protocols and 27.5% were foreign protocols (table 5A). Clinical studies not included in this analysis are those studies that have just begun and have not reported enrollment data or have not begun recruiting patients. A total of 652,300 participants were enrolled in extramural and intramural Phase III research protocols of which 84.1% were domestic participants and 15.9% were foreign participants (table 5B). Of the 652,300 participants, 53.0% were women, 42.3% were men and 4.7% did not provide sex identification (table 5B). Further, 44.8% of the total participants, and 38.6% of Domestic-only participants, in Phase III clinical research were reported as minorities following the current OMB categories for race and ethnicity (table 5C).

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

Moreover, in FY 2009, 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 4D).

Accordingly, minority representation by race was highest for Blacks at 23.9% and lowest for Hawaiian/Pacific Islanders at 0.2% (table 4C). Asians represented 19.1%, American Indian/Alaska Natives 3.6% and Whites 39.0% of participants (table 4C). Participants identifying as *More Than One* Race were 1.0% of the total number of participants (table 4C). In addition, 13.3% did not identify a race category (table 4C). Of the 434 extramural and intramural Phase III research protocols designating an ethnicity in FY2008, 80.6 % of total participants identified as "Not Hispanic", 10.7% of the total participants identified as "Hispanic or Latino", and 8.7% of the total participants did not identify an ethnicity category (table 4C). The racial distribution of the "Hispanic or Latino" participants is also provided separately (table 4D)**.**

The number of participants in Phase III extramural and intramural clinical research in FY2009, 652,300, remained within the ranges reported since FY1995. Similarly, the proportion of males and females, 53.0%F and 42.3%M in FY2009, is similar to previous years (table 4A).

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

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2008 and 2009

In FY2008, there were 13,725 extramural clinical research protocols, including Phase III and other clinical studies, of which 9,381 protocols reported human subject participation (table 6A). Of these, 95.6% were domestic protocols and 4.4% were foreign protocols (table 6A). Approximately 12.6 million participants were enrolled in extramural research protocols of which 93.8% of the total enrollment is domestic participants and 6.2% of the total enrollment is foreign participants (table 6B). Of the 12.6 million participants, 63.84% were women, 35.04% were men and 1.12% did not provide sex identification (table 7A). Further, 29.38% of the total participants were reported as minorities following the current OMB categories for race and ethnicity (table 7A).

Correspondingly, 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, 91.5% were domestic protocols and 8.5% were foreign protocols (table 8A). Approximately 16.2 million participants were enrolled in extramural research protocols of which 96.0% of the total enrollment is domestic participants and 4.0% of the total enrollment is foreign participants (table 8A). Of the 16.2 million participants, 62.94% were women, 36.54% were men and 0.52% did not provide sex identification (table 9A). Further, 30.39% of the total extramural participants were reported as minorities following the current OMB categories for race and ethnicity (table 9A).

While the number of participants in extramural clinical research protocols increased (12.6 million in FY2008 and 16.2 million in FY2009), there was no significant change in the proportions of women and men (63.84%F and 35.04%M in FY2008 and 62.94%F and 36.54%M in FY2009). When sex-specific studies were excluded, the proportions of women and men in extramural clinical research reported in FY2008 were 45.61% for females and 52.60% for males (table 10A), and in FY2009 50.22% for females and 49.03% for males (table 11A).

NIH Defined Phase III Extramural Clinical Research: FY2008 and FY2009

In FY2008 there were 696 extramural Phase III clinical research protocols, of which 602 protocols reported human subject participation (table 12A). A total of 776,034 participants were enrolled in extramural Phase III research protocols of which 57.22% were women, 40.58% were men and 2.19% did not provide sex identification (table 13A).

In FY2008 there were 452 extramural Phase III research protocols reporting data following the current OMB standards for reporting race and ethnicity (table 13B). Minority representation by race was highest for Blacks at 18.68% and lowest for Hawaiian/Pacific Islanders 0.12% (table 13B). Asians represented 17.41%, American Indian/Alaska Natives 2.74% and Whites 51.22% of participants (table 13B). Participants identifying as *More Than One* Race were 2.22% of the total number of participants (table 13B). In addition, 7.62% did not identify a race category (table 13B). Of the 452 extramural Phase III research protocols designating an ethnicity in FY 2008, 83.84% of total participants identified as "Not Hispanic", 10.38% of the total participants identified as "Hispanic or Latino", and 5.78% of the total participants did not identify an ethnicity category (table 13B). The racial distribution of the "Hispanic or Latino" participants is also provided separately (table 13B).

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 52.60% were women, 42.62% were men and 4.78% did not provide sex identification (table 15A).

Correspondingly in FY2009, there were 407 extramural Phase III research protocols reporting data following the current OMB standards for reporting race and ethnicity (table 15A). Minority representation by race was highest for Blacks at 24.36% and lowest for Hawaiian/Pacific Islanders 0.18%. Asians represented 19.62%, American Indian/Alaska Natives 3.66% and Whites 39.93% of participants (table 15A). Participants identifying as *More Than One* Race were 0.99% of the total number of participants (table 15A). In addition, 11.26 % did not identify a race category (table 15A). Of the 407 extramural Phase III research protocols designating an ethnicity in FY 2009, 82.29 % of total participants identified as "Not Hispanic", 9.41% of the total participants identified as "Hispanic or Latino", and 8.29 % of the total participants did not identify an ethnicity category (table 15A). The racial distribution of the "Hispanic or Latino" participants is also provided separately (table 15A).

While the number of extramural Phase III clinical research protocols decreased (696 in FY2008 and 619 in FY2009) there was a slight decrease in the proportion of women (57.2%F and 40.6%M in FY2008 and 52.60%F and 42.62%M in FY2009) and an increase in those not providing sex identification (2.19% in FY2008 and 4.78% in FY2009).

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2008 and 2009

In FY2008 there were 1,873 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,664 protocols reported human subject participation (table 6A). Approximately 2.8 million participants were enrolled in intramural research protocols of which 42.82% were women, 55.93% were men and 1.25% did not provide sex identification (table 16A).

In FY2008, approximately 2.8 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies (table 16A). Of the 413 intramural research protocols that report data following the former OMB standards, minority representation was highest for Blacks (not Hispanic) at 30.34% and lowest for American Indian/Alaska Natives at 0.15% (table 16C). Asian/Pacific Islanders represented 3.38%, Hispanics 4.02%, and Whites (not Hispanic) 60.73% of the intramural research study population (table 16C). The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards.

For the 1,251 intramural clinical research studies that reported data following the current OMB standards in FY 2008, the largest racial minority group was Asians at 9.80% and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.17% (table 16B). Blacks represented 9.40%, American Indian/Alaska Natives 0.81% and Whites 67.92% of participants in all intramural clinical research (table 16B).

Approximately 0.61% of participants reported *More Than One Race* as their racial category. In addition, 11.29 % did not identify a race category (table 16B). Of the 1,251intramural research protocols following the current OMB standards designating an ethnicity in FY2008, 85.30% of total participants identified as "Not Hispanic", 4.07% of the total participants identified as "Hispanic or Latino", and 10.62% of the total participants did not identify an ethnicity category (table 16B). The racial distribution of the "Hispanic or Latino" participants is also provided separately (table 16B).

Correspondingly, 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 42.38% were women, 56.10% were men and 1.52% did not provide sex identification (table 17).

In FY 2009, approximately 3.0 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies (table 17). Of the 392 intramural research protocols that report data following the former OMB standards, minority representation was highest for Blacks (not Hispanic) at 13.60% and lowest for American Indian/Alaska Natives at 0.17% (table 17). Asian/Pacific Islanders represented 4.18%, Hispanics 5.62%, and Whites (not Hispanic) 74.94% of the intramural research study population (table 17). The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards.

For the 1,335 intramural clinical research studies that reported data following the current OMB standards in FY 2009, the largest racial minority group was Asians at 9.99 % and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.05% (table 17). Blacks represented 9.76%, American Indian/Alaska Natives 0.75% and Whites 63.50% of participants in all intramural clinical research (table 17). Approximately 5.48% of participants reported *More Than One Race* as their racial category (table 17). In addition, 10.48 % did not identify a race category (table 17). Of the 1,335 intramural research protocols following the current OMB standards designating an ethnicity in FY2009, 81.24 % of total participants identified as "Not Hispanic", 3.96% of the total participants identified as "Hispanic or Latino", and 14.80% of the total participants did not identify an ethnicity category (table 17). The racial distribution of the "Hispanic or Latino" participants is also provided separately (table 17).

While the number of participants in intramural clinical research protocols slightly increased (2.8M in FY2008 and 3.0M in FY2009), there was no substantive change in the proportions of women and men (42.82%F and 55.93%M in FY2008 and 42.38%F and 56.10%M in FY2009).

NIH Defined Phase III Intramural Clinical Research: FY2008 and FY2009

In FY2008 there were 39 intramural Phase III clinical research protocols, of which 37 protocols reported human subject participation (table 12A). Of these, 89.2% of the total number of protocols are domestic and 10.8% of the total number of protocols is foreign (table 12A). A total of 16,544 participants were enrolled in intramural Phase III research protocols of which 36.8% are domestic participants and 63.2% are foreign participants (table 12B). Of the 16,544 participants, 69.71% were women, 28.92% were men and 1.37% did not provide sex identification (table 18A). Further, 56.67% of total participants in Phase III intramural clinical research protocols were reported as minorities following the current OMB categories for race and ethnicity (table 18A).

Correspondingly, 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 is 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% of the total enrollment is domestic participants and 63.6% are foreign participants (table 14B). Of the 16,475 participants, 68.70% were women, 31.22% were men and 0.08% did not provide sex identification (table 19). Further, 56.10% of total participants in Phase III clinical research protocols were reported as minorities following the OMB categories for race and ethnicity (table 19).

While the number of participants specifically in Phase III intramural clinical research protocols slightly decreased (16,544 in FY2008 and 16,475 in FY2009), there was very little change in the proportions of women (69.71%F and 28.92%M in FY2008 and 68.70%F and 31.22%M in FY2008).

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY1995 – FY2009

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 20B is a fifteen 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 11,171 in FY2009 – a 3.5 fold increase (table 20A). Reported enrollment increased from approximately 1.0 million (FY1995) to 19.1 million (FY2009) – an 18.7 fold increase; minority enrollment increased from approximately 0.4 million (FY1995) to 5.8 million (FY2009) – a 15.4 fold increase in the number of minority participants in NIH clinical research (5A). 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 18.0 million (FY2009) – a 1.8 fold increase (table 20A). Foreign enrollment increased from 0.9 million (FY2002) to 1.2 million (FY2009) – a 1.2 fold increase (table 20A). Overall, the total enrollment has increased with domestic participation ranging between 75.9 to 93.9.7% and foreign participation ranging between 6.1 to 24.1%. In FY2009, domestic and foreign enrollment was 93.9% and 6.1% respectively (table 20C).

Table 21 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 21A). Overall minority participation in all extramural and intramural clinical research ranged between 28.6% and 43.1% (table 21A). Table 21E provides a comparison of domestic and foreign participation between FY2002 and FY2009. 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 21F shows domestic and foreign minority enrollment for the eight-year period (FY2002-FY2009). Minority enrollment varied between 24.1% and 28.9% of total domestic participation, while minority enrollment varied between 66.8% and 90.9% of total foreign participation (table 21F).

Table 4 is a summary of NIH-funded Phase III extramural and intramural clinical research by sex/gender and minority enrollment following the old and new data reporting formats for domestic and foreign studies. This table demonstrates that female participation in NIH funded Phase III extramural and intramural clinical research generally ranged between 54.1% and 74.8% and male participation in NIH-funded Phase III extramural and intramural clinical research ranged between 24.3% and 44.6% (table 4A). Overall minority participation in NIH-funded Phase III extramural and intramural clinical research ranged from 22.5% to 44.8% (table 4A). Table 4E provides a comparison of domestic and foreign participation between FY2002 and FY2009. 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 4F shows domestic and foreign enrollment for the same eight-year period. Minority enrollment varied between 20.2% and 38.6% 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.

Tables 22-25 summarize participation for domestic and foreign protocols for NIH funded clinical research including NIH Phase III clinical research. For extramural and intramural clinical research, participants enrolled in domestic protocols, female participation ranged between 58.1% and 67.3% while male participation ranged between 31.2 and 39.5% (table 22A). For NIH-funded Phase III extramural and intramural clinical research, participants enrolled in domestic protocols, female participation ranged between 52.4% and 64.6% while male participation ranged between 34.4% and 44.8% (table 23A). For all extramural and intramural clinical research, participants enrolled in foreign protocols, female participation varied from 39.2% to 59.5% while male participation varied from 39.3% to 60.4% (table 24A). For NIH-funded Phase III extramural and intramural clinical research, participants enrolled in foreign protocols, female participation varied from 47.4% to 59.2% while male participation varied from 40.4% to 52.5% (table 25A).

Aggregate Enrollment Data Tables
For Extramural and Intramural Research Protocols

Fiscal Year 2009 Summary Reports
Fifteen -year Trend Summary Reports

Table 1. Summary of NIH Clinical Research Reported In FY2008: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

1A. PROTOCOLS REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Protocols with Enrollment	11,045	10,548	95.5%	497	4.5%
%	70.8%	70.9%		68.7%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,553	4,327	95.0%	226	5.0%
	29.2%	29.1%		31.3%	
Total Number of Protocols	**15,598**	**14,875**	95.4%	**723**	4.6%
%	100.0%	100.0%		100.0%	

1B. ENROLLMENT REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Females Enrolled	9,243,966	8,514,768	92.1%	729,198	7.9%
%	60.0%	60.2%		57.1%	
Males Enrolled	5,991,739	5,451,624	91.0%	540,115	9.0%
%	38.9%	38.6%		42.3%	
Sex of Subjects is Unknown	176,650	168,235	95.2%	8,415	4.8%
%	1.1%	1.2%		0.7%	
Total Subjects Enrolled	**15,412,355**	**14,134,627**	91.7%	**1,277,728**	8.3%
%	100.0%	100.0%		100.0%	

1C. MINORITY ENROLLMENT REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Minority Total**	**4,386,636**	**3,521,691**	80.3%	**864,945**	19.7%
% Minority Enrollment	**28.5%**	**24.9%**		67.7%	

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

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

Table 2. Summary of NIH Clinical Research Reported In FY2009: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

2A. PROTOCOLS REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Protocols with Enrollment	11,171	10,269	91.9%	902	8.1%
%	66.9%	65.9%		81.2%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	5,518	5,309	96.2%	209	3.8%
	33.1%	34.1%		18.8%	
Total Number of Protocols	**16,689**	**15,578**	93.3%	**1,111**	6.7%
%	100.0%	100.0%		100.0%	

2B. ENROLLMENT REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Females Enrolled	11,439,143	10,748,744	94.0%	690,399	6.0%
%	59.8%	59.8%		58.7%	
Males Enrolled	7,570,646	7,093,702	93.7%	476,944	6.3%
%	39.6%	39.5%		40.6%	
Sex of Subjects is Unknown	128,949	120,433	93.4%	8,516	6.6%
%	0.7%	0.7%		0.7%	
Total Subjects Enrolled	**19,138,738**	**17,962,879**	93.9%	**1,175,859**	6.1%
%	100.0%	100.0%		100.0%	

2C. MINORITY ENROLLMENT REPORTED	**Total All Clinical Studies***	**Domestic**	**%**	**Foreign**	**%**
Minority Total**	**5,783,543**	**4,998,599**	86.4%	**784,944**	13.6%
% Minority Enrollment	**30.2%**	**27.8%**		66.8%	

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

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

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2008: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

3A. PROTOCOLS REPORTED	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Protocols with Enrollment	639	585	91.5%	54	8.5%
%	88.0%	88.1%		87.1%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	87	79	90.8%	8	9.2%
	12.0%	11.9%		12.9%	
Total Number of Protocols	**726**	**664**	91.5%	**62**	8.5%
%	100.0%	100.0%		100.0%	

3B. ENROLLMENT REPORTED	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Females Enrolled	455,590	347,982	76.4%	107,608	23.6%
%	57.5%	58.9%		53.4%	
Males Enrolled	319,754	226,266	70.8%	93,488	29.2%
%	40.3%	38.3%		46.4%	
Sex of Subjects is Unknown	17,234	16,857	97.8%	377	0.0%
%	2.2%	2.9%		0.2%	
Total Subjects Enrolled	**792,578**	**591,105**	74.6%	**201,473**	25.4%
%	100.0%	100.0%		100.0%	

3C. MINORITY ENROLLMENT REPORTED**	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Minority Total for all Phase III studies	**308,433**	**119,582**	38.8%	**188,851**	61.2%
	38.9%	20.2%		93.7%	

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

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

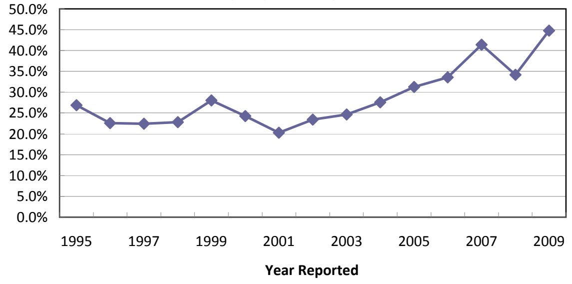
NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Table 4: Fifteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2009: Enrollment by Race and Ethnicity

4A. Phase III FIFTEEN YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER IN ALL

FY Reported	FY Funded	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms):
1995	1994	171,181	108,324	19,818	299,323	80,562	560
	%	57.2%	36.2%	6.6%	100.0%	26.9%	
1996	1995	264,755	203,698	21,210	489,663	110,669	608
	%	54.1%	41.6%	4.3%	100.0%	22.6%	
1997	1996	264,755	203,698	21,210	489,663	110,000	608
	%	54.1%	41.6%	4.3%	100.0%	22.5%	
1998	1997	228,417	74,389	2,705	305,511	69,599	320
	%	74.8%	24.3%	0.9%	100.0%	22.8%	
1999	1998	339,533	163,950	1,446	504,929	141,449	578
	%	67.2%	32.5%	0.3%	100.0%	28.0%	
2000	1999	313,952	180,705	1,086	495,743	120,339	589
	%	63.3%	36.5%	0.2%	100.0%	24.3%	
2001	2000	412,379	168,085	1,273	581,737	117,873	645
	%	70.9%	28.9%	0.2%	100.0%	20.3%	
2002	2001	278,876	195,090	781	474,747	111,269	754
	%	58.7%	41.1%	0.2%	100.0%	23.4%	
2003	2002	294,950	239,403	1,914	536,267	132,302	852
	%	55.0%	44.6%	0.4%	100.0%	24.7%	
2004	2003	301,353	242,913	1,101	545,367	150,456	573
	%	55.3%	44.5%	0.2%	100.0%	27.6%	
2005	2004	290,977	197,300	4,723	493,000	154,191	547
		59.0%	40.0%	1.0%	100.0%	31.3%	
2006	2005	314,066	179,975	5,389	499,430	167,446	624
		62.9%	36.0%	1.1%	100.0%	33.5%	
2007	2006	324,694	249,633	16,832	591,159	244,932	621
		54.9%	42.2%	2.8%	100.0%	41.4%	
2008	2007	455,612	319,732	17,234	792,578	270,899	639
		57.5%	40.3%	2.2%	100.0%	34.2%	
2009	2008	345,748	276,159	30,393	652,300	291,949	630
		53.0%	42.3%	4.7%	100.0%	44.8%	

Percentage of Enrollment as Minority in Phase III Clinical Study Reported by Year



Sex/Gender Phase III Enrollment by Year Reported

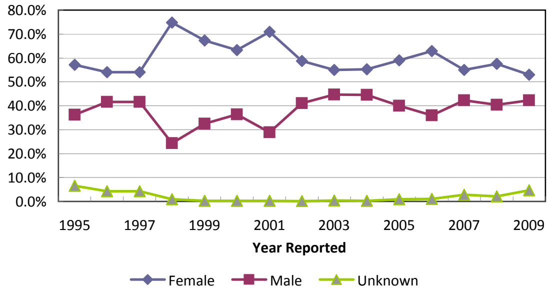


Table 4A Comments:

1. Table 4A summarizes enrollment by sex/gender and minority race/ethnicity categories for the fifteen year reporting period (1995-2009). The data are

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).

Table 4: Fifteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2009: Enrollment by Race and Ethnicity

Notes Tables 4B-D

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

NOTE 2: Data from Tables 4B, 4C and 4D are combined to provide the summary data in Table 4A.

4B. Phase III OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other		Total	Subtotal Using US Minority Categories (shaded): OLD FORM		Number Protocols with Enrollment data (Old Form):
1995	**1994**	5,358	2,740	52,433	20,031	172,773	45,988		299,323	80,562		560
	%	1.8%	0.9%	17.5%	6.7%	57.7%	15.4%		100.0%	26.9%		
1996	**1995**	4,235	40,126	46,838	19,470	321,445	57,549		489,663	110,669		608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%		100.0%	22.6%		
1997	**1996**	4,235	40,126	46,838	19,470	321,445	57,549		489,663	110,669		608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%		100.0%	22.6%		
1998	**1997**	5,030	5,324	42,805	16,440	229,534	6,378		305,511	69,599		320
	%	1.6%	1.7%	14.0%	5.4%	75.1%	2.1%		100.0%	22.8%		
1999	**1998**	3,685	20,276	76,921	40,567	336,703	26,777		504,929	141,449		578
	%	0.7%	4.0%	15.2%	8.0%	66.7%	5.3%		100.0%	28.0%		
2000	**1999**	3,726	24,017	62,512	30,084	335,824	39,580		495,743	120,339		589
	%	0.8%	4.8%	12.6%	6.1%	67.7%	8.0%		100.0%	24.3%		
2001	**2000**	4,079	11,132	70,110	32,552	422,802	41,062		581,737	117,873		645
	%	0.7%	1.9%	12.1%	5.6%	72.7%	7.1%		100.0%	20.3%		
2002	**2001**	1,645	20,560	51,991	29,636	315,543	12,228		431,603	103,832		**660**
	%	0.38%	4.8%	12.0%	6.9%	73.1%	2.8%		100.00%	24.1%		
2003	**2002**	1,689	20,038	49,255	29,066	337,654	16,615		454,317	100,048		**656**
	%	0.4%	4.4%	10.8%	6.4%	74.3%	3.7%		100.0%	22.0%		
2004	**2003**	1,505	18,807	45,285	32,974	265,764	14,050		378,385	98,571		**296**
	%	0.4%	5.0%	12.0%	8.7%	70.2%	3.7%		100.0%	26.1%		
2005	**2004**	1,319	17,740	39,402	21,829	231,492	4,507		316,289	80,290		**210**
	%	0.4%	5.6%	12.5%	6.9%	73.2%	1.4%		100.0%	25.4%		
2006	**2005**	1,012	16,800	20,355	9,524	175,724	6,348		229,763	47,691		**215**
	%	0.4%	7.3%	8.9%	4.1%	76.5%	2.8%		100.0%	20.8%		
2007	**2006**	751	3,943	21,582	9,333	169,789	4,259		209,657	35,609		**197**
	%	0.4%	1.9%	10.3%	4.5%	81.0%	2.0%		100.0%	17.0%		
2008	**2007**	900	4,542	22,445	9,642	190,753	4,262		232,544	37,529		**164**
	%	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**
	%	0.4%	2.0%	9.0%	3.9%	82.1%	2.6%		100.0%	15.3%		

1. The New Form consists of Parts A and B (Tables 4C and 4D) for reporting years 2002-2009. This Form is provided as part of the annual progress report.

2. Table 4C displays the New Form Part A for reporting separate race and ethnicity data.

3. Table 4D 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.

4C. Phase III New Form: Total of All Subjects Reported Using the 1997 OMB Standards for

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
2002	**2001**	159	799	4,647	52	34,654	560	2,273	43,144	36,224	1,629	5,291	43,144
	%	0.37%	1.85%	10.77%	0.12%	80.32%	1.30%	5.27%	100.00%	83.96%	3.78%	12.26%	100.00%
2003	**2002**	484	2,609	21,641	220	47,869	989	8,138	81,950	64,295	7,831	9,824	81,950
	%	0.6%	3.2%	26.4%	0.3%	58.4%	1.2%	9.9%	100.0%	78.5%	9.6%	12.0%	100.0%
2004	**2003**	1,396	4,385	43,721	611	106,793	4,419	5,657	166,982	145,742	13,435	7,805	166,982
	%	0.8%	2.6%	26.2%	0.4%	64.0%	2.6%	3.4%	100.0%	87.3%	8.0%	4.7%	100.0%
2005	**2004**	2,164	9,192	50,338	462	101,238	3,063	10,254	176,711	156,650	10,397	9,664	176,711
	%	1.2%	5.2%	28.5%	0.3%	57.3%	1.7%	5.8%	100.0%	88.6%	5.9%	5.5%	100.0%
2006	**2005**	4,630	32,360	50,780	535	126,670	4,246	50,446	269,667	202,358	31,034	36,275	269,667
	%	1.7%	12.0%	18.8%	0.2%	47.0%	1.6%	18.7%	100.0%	75.0%	11.5%	13.5%	100.0%
2007	**2006**	9,351	47,364	84,468	555	133,002	4,145	102,617	381,502	254,692	71,622	55,188	381,502
	%	2.5%	12.4%	22.1%	0.1%	34.9%	1.1%	26.9%	100.0%	66.8%	18.8%	14.5%	100.0%
2008	**2007**	15,006	95,296	103,166	716	281,344	12,136	52,370	560,034	460,862	64,351	34,821	560,034
	%	2.7%	17.0%	18.4%	0.1%	50.2%	2.2%	9.4%	100.0%	82.3%	11.5%	6.2%	100.0%
2009	**2008**	17,509	92,868	116,233	859	189,527	4,676	64,891	486,563	391,990	52,223	42,350	486,563
	%	3.6%	19.1%	23.9%	0.2%	39.0%	1.0%	13.3%	100.0%	80.6%	10.7%	8.7%	100.0%

Table 4: Eight Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2009: Enrollment by Race and Ethnicity

4D. Phase III Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Protocols with Enrollment data (New Form):
2002	2001	49	22	31	4	660	304	560	1,630	**7,437**		**94**
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	17.2%		
2003	2002	37	70	186	23	2,115	203	5,197	7,831	**32,254**		**196**
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	39.4%		
2004	2003	269	59	193	26	7,264	3,052	2,572	13,435	**54,405**		**277**
	%	2.0%	0.4%	1.4%	0.2%	54.1%	22.7%	19.1%	100.0%	32.6%		
2005	2004	759	42	446	45	3,667	423	5,015	10,397	**73,901**		**337**
	%	7.3%	0.4%	4.3%	0.4%	35.3%	4.1%	48.2%	100.0%	41.8%		
2006	2005	2,307	50	720	40	6,872	713	20,332	31,034	**119,755**		**409**
	%	7.4%	0.2%	2.3%	0.1%	22.1%	2.3%	65.5%	100.0%	44.4%		
2007	2006	7,333	45	458	24	7,430	322	56,010	71,622	**209,323**		**424**
	%	10.2%	0.1%	0.6%	0.0%	10.4%	0.4%	78.2%	100.0%	54.9%		
2008	2007	13,060	229	717	122	22,293	5,654	22,276	64,351	**270,889**		**475**
	%	20.3%	0.4%	1.1%	0.2%	34.6%	8.8%	34.6%	100.0%	48.4%		
2009	2008	15,313	351	937	198	11,487	964	22,973	52,223	**266,605**		**434**
	%	29.3%	0.7%	1.8%	0.4%	22.0%	1.8%	44.0%	100.0%	54.8%		

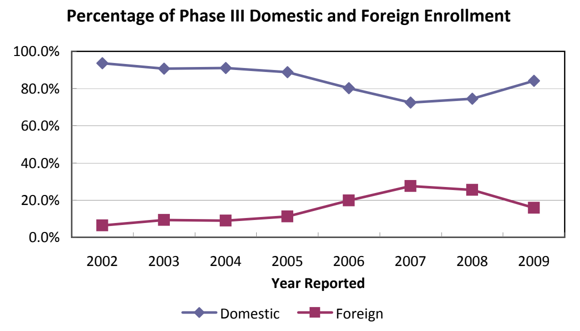
*** These totals must agree**

**** These totals must agree**

29.32%

4E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2009

		ENROLLMENT					PROTOCOLS				
FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC	Percent DOMESTIC	Total FOREIGN	Percent FOREIGN	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols	Percent Domestic Protocols	Number of FOREIGN Protocols	Percent Foreign Protocols
2002	2001	474,747	444,436	93.6%	30,311	6.4%	754	582	77.2%	172	22.8%
2003	2002	536,267	486,857	90.8%	49,410	9.2%	852	643	75.5%	209	24.5%
2004	2003	545,367	496,241	91.0%	49,126	9.0%	573	549	95.8%	24	4.2%
2005	2004	493,000	437,902	88.8%	55,098	11.2%	547	517	94.5%	30	5.5%
2006	2005	499,430	400,297	80.2%	99,133	19.8%	624	564	90.4%	60	9.6%
2007	2006	591,159	428,440	72.5%	162,719	27.5%	653	609	93.3%	44	6.7%
2008	2007	792,578	591,105	74.6%	201,473	25.4%	639	585	91.5%	54	8.5%
2009	2008	652,300	548,700	84.1%	103,600	15.9%	630	457	72.5%	173	27.5%


Percentage of Phase III Domestic and Foreign Enrollment

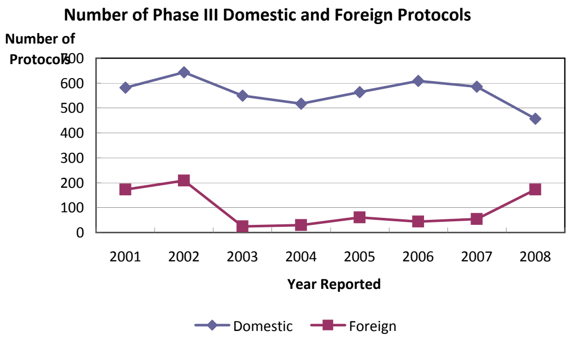

Number of Phase III Domestic and Foreign Protocols

Table 4: Eight Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2009: Enrollment by Race and Ethnicity

4F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2009

FY Reported	FY Funded	FOREIGN Phase III Minority	FOREIGN Phase III Total	DOMESTIC Phase III Minority	DOMESTIC Phase III Total
2002	**2001**	**18,308**	**30,311**	**92,961**	**444,436**
		60.4%	100.0%	20.9%	100.0%
2003	**2002**	**23,927**	**49,410**	**109,376**	**486,857**
		48.4%	100.0%	22.5%	100.0%
2004	**2003**	**37,126**	**49,126**	**125,813**	**496,241**
		75.6%	100.0%	25.4%	100.0%
2005	**2004**	**44,281**	**55,098**	**109,910**	**437,902**
		80.4%	100.0%	25.1%	100.0%
2006	**2005**	**84,412**	**99,133**	**83,034**	**400,297**
		85.2%	100.0%	20.7%	100.0%
2007	**2006**	**156,533**	**162,713**	**79,769**	**383,050**
		96.2%	100.0%	20.8%	100.0%
2008	**2007**	**188,851**	**201,473**	**119,582**	**591,105**
		93.7%	100.0%	20.2%	100.0%
2009	**2008**	**80,065**	**103,600**	**211,884**	**548,700**
		77.3%	100.0%	38.6%	100.0%

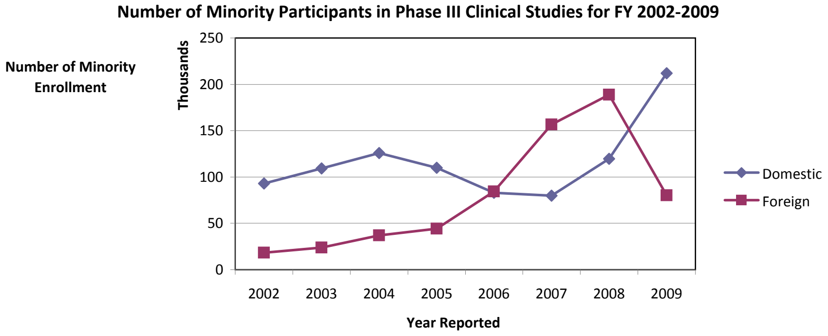


Table 5. Summary of NIH Phase III Clinical Research Reported In FY2009: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

5A. PROTOCOLS REPORTED	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Protocols with Enrollment	630	457	72.5%	173	27.5%
%	95.2%	94.2%		97.7%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	32	28	87.5%	4	12.5%
	4.8%	5.8%		2.3%	
Total Number of Protocols	**662**	**485**	73.3%	**177**	26.7%
%	100.0%	100.0%		100.0%	

5B. ENROLLMENT REPORTED	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Females Enrolled	345,748	287,455	83.1%	58,293	16.9%
%	53.0%	52.4%		56.3%	
Males Enrolled	276,159	231,173	83.7%	44,986	16.3%
%	42.3%	42.1%		43.4%	
Sex of Subjects is Unknown	30,393	30,072	98.9%	321	0.0%
%	4.7%	5.5%		0.3%	
Total Subjects Enrolled	**652,300**	**548,700**	84.1%	**103,600**	15.9%
%	100.0%	100.0%		100.0%	

5C. MINORITY ENROLLMENT REPORTED	**Total of Phase III Clinical Trials***	**Domestic**	**%**	**Foreign**	**%**
Minority Total for all Phase III studies	**291,949**	**211,884**	72.6%	**80,065**	27.4%
	44.8%	38.6%		77.3%	

* 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 6: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2008: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

		Domestic				Foreign			
6A. PROTOCOLS REPORTED	**Total All Clinical Studies**	**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
Number of Protocols reporting females only	1,272	1,104	86.8%	121	9.5%	40	3.1%	7	0.6%
%	8.2%	8.4%		6.8%		6.4%		7.2%	
Number of Protocols reporting males only	529	480	90.7%	26	4.9%	18	3.4%	5	0.9%
%	3.4%	3.7%		1.5%		2.9%		5.2%	
Number of Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)	9,244	7,387	79.9%	1,430	15.5%	352	3.8%	75	0.8%
%	59.3%	56.4%		80.5%		56.2%		77.3%	
Total Number of Protocols with Enrollment	**11,045**	**8,971**	81.2%	**1,577**	14.3%	**410**	3.7%	**87**	0.8%
%	70.8%	68%		88.8%		65.5%		89.7%	
Number of Protocols with zero enrollment. Enrollment data has not yet been submitted.	4,553	4,128	90.7%	199	4.4%	216	4.7%	10	0.2%
%	29.2%	31.5%		11.2%		34.5%		10.3%	
Total Number of Protocols	**15,598**	**13,099**	84.0%	**1,776**	11.4%	**626**	4.0%	**97**	0.6%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

		Domestic				Foreign			
6B. ENROLLMENT REPORTED	**Total All Clinical Studies**	**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
In Protocols reporting females only	7,507,149	6,805,570	90.7%	401,336	5.3%	142,737	1.9%	157,506	2.1%
%	48.7%	57.7%		17.2%		18.3%		31.6%	
In Protocols reporting males only	361,434	314,494	87.0%	7,670	2.1%	12,319	3.4%	26,951	7.5%
%	2.3%	2.7%		0.3%		1.6%		5.4%	
In Protocols excluding female-only and male-only enrollment protocols	7,543,772	4,677,541	62.0%	1,928,016	25.6%	624,208	8.3%	314,007	4.2%
%	48.9%	39.6%		82.5%		80.1%		63.0%	
Enrollment Totals for all studies	**15,412,355**	**11,797,605**	76.5%	**2,337,022**	15.2%	**779,264**	5.1%	**498,464**	3.2%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

		Domestic				Foreign			
6C. MINORITY ENROLLMENT REPORTED**		**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
Minority Totals for all studies	**4,416,770**	**3,092,465**	70.0%	**459,360**	10.4%	**603,124**	13.7%	**261,821**	5.9%
% Minority enrollment	28.7%	26.2%		19.7%		77.4%		52.5%	

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

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

Table 7. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

7A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**8,029,181**	**2,263,551**		**28.19%**
%	**63.84%**	**61.25%**		
Males	**4,406,583**	**1,414,608**		**32.10%**
%	**35.04%**	**38.28%**		
Unknown	**141,104**	**17,429**		**12.35%**
%	**1.12%**	**0.47%**		
TOTAL	**12,576,868**	**3,695,588**	**29.38%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	9,381

7B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 8,879

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	78,464	618,320	867,547	26,282	4,932,495	100,278	1,097,714	7,721,100	6,099,147	620,632	1,001,322	7,721,101
	0.65%	**5.09%**	**7.14%**	**0.22%**	**40.60%**	**0.83%**	**9.04%**	**63.55%**	**50.20%**	**5.11%**	**8.24%**	**63.55%**
	1.02%	*8.01%*	*11.24%*	*0.34%*	*63.88%*	*1.30%*	*14.22%*	*100.00%*	*78.99%*	*8.04%*	*12.97%*	*100.00%*
	69.79%	67.98%	54.55%	59.72%	62.75%	60.49%	74.91%	63.55%	63.30%	61.49%	66.58%	63.55%
Male	33,452	289,799	715,125	17,520	2,920,167	64,052	246,846	4,286,961	3,521,042	382,036	383,883	4,286,961
	0.28%	**2.39%**	**5.89%**	**0.14%**	**24.04%**	**0.53%**	2.03%	**35.29%**	**28.98%**	**3.14%**	**3.16%**	**35.29%**
	0.78%	*6.76%*	*16.68%*	*0.41%*	*68.12%*	*1.49%*	5.76%	*100.00%*	*82.13%*	*8.91%*	*8.95%*	*100.00%*
	29.75%	31.86%	44.96%	39.81%	37.15%	38.64%	16.85%	35.29%	36.54%	37.85%	25.53%	35.29%
Unknown	517	1,479	7,813	204	8,468	1,435	120,805	140,721	15,345	6,668	118,708	140,721
	0.00%	**0.01%**	**0.06%**	0.00%	**0.07%**	**0.01%**	*0.99%*	**1.16%**	**0.13%**	**0.05%**	**0.98%**	**1.16%**
	0.37%	*1.05%*	*5.55%*	0.14%	*6.02%*	*1.02%*	*85.85%*	*100.00%*	*10.90%*	*4.74%*	*84.36%*	*100.00%*
	0.46%	0.16%	0.49%	0.46%	0.11%	0.87%	8.24%	1.16%	0.16%	0.66%	7.89%	1.16%
Total	112,433	909,598	1,590,485	44,006	7,861,130	165,765	1,465,365	12,148,782	9,635,534	1,009,336	1,503,913	12,148,783
	0.93%	**7.49%**	**13.09%**	**0.36%**	**64.71%**	**1.36%**	**12.06%**	**100.00%**	**79.31%**	**8.31%**	**12.38%**	**100.00%**
	0.93%	*7.49%*	*13.09%*	*0.36%*	*64.71%*	*1.36%*	*12.06%*	*100.00%*	*79.31%*	*8.31%*	*12.38%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	18,647	17,212	27,081	1,360	316,968	31,241	208,123	620,632	2,215,982
	1.85%	**1.71%**	**2.68%**	**0.13%**	**31.40%**	**3.10%**	**20.62%**	**61.49%**	**18.24%**
	3.00%	*2.77%*	*4.36%*	*0.22%*	*51.07%*	*5.03%*	*33.53%*	*100.00%*	*28.70%*
	54.51%	54.50%	32.96%	58.17%	68.95%	54.97%	60.77%	61.49%	61.14%
Male	15,384	14,252	54,818	941	141,977	25,477	129,187	382,036	1,391,112
	1.52%	**1.41%**	**5.43%**	**0.09%**	**14.07%**	**2.52%**	**12.80%**	**37.85%**	**11.45%**
	4.03%	*3.73%*	*14.35%*	*0.25%*	*37.16%*	*6.67%*	*33.82%*	*100.00%*	*32.45%*
	44.97%	45.13%	66.72%	40.25%	30.88%	44.83%	37.72%	37.85%	38.38%
Unknown	179	116	260	37	778	114	5,184	6,668	17,410
	0.02%	**0.01%**	**0.03%**	**0.00%**	**0.08%**	**0.01%**	**0.51%**	**0.66%**	**0.14%**
	2.68%	*1.74%*	*3.90%*	*0.55%*	*11.67%*	*1.71%*	*77.74%*	*100.00%*	*12.37%*
	0.52%	0.37%	0.32%	1.58%	0.17%	0.20%	1.51%	0.66%	0.48%
TOTAL	34,210	31,580	82,159	2,338	459,723	56,832	342,494	1,009,336	3,624,504
	3.39%	**3.13%**	**8.14%**	**0.23%**	**45.55%**	**5.63%**	**33.93%**	**100.00%**	**29.83%**
	3.39%	*3.13%*	*8.14%*	*0.23%*	*45.55%*	*5.63%*	*33.93%*	*100.00%*	*29.83%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 7

7C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: **502**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	1,243	7,330	26,019	12,977	250,613	9,899	308,081	47,569
	0.29%	**1.71%**	**6.08%**	**3.03%**	**58.54%**	**2.31%**	**71.97%**	**11.11%**
	0.40%	*2.38%*	*8.45%*	*4.21%*	*81.35%*	*3.21%*	*100.00%*	*15.44%*
	76.49%	77.00%	66.54%	62.28%	73.69%	58.47%	71.97%	66.92%
Male	382	2,176	13,082	7,856	89,286	6,840	119,622	23,496
	0.09%	**0.51%**	**3.06%**	**1.84%**	**20.86%**	**1.60%**	**27.94%**	**5.49%**
	0.32%	*1.82%*	*10.94%*	*6.57%*	*74.64%*	*5.72%*	*100.00%*	*19.64%*
	23.51%	22.86%	33.45%	37.71%	26.25%	40.40%	27.94%	33.05%
Unknown	0	13	4	2	174	190	383	19
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.04%**	**0.04%**	**0.09%**	**0.00%**
	0.00%	*3.39%*	*1.04%*	*0.52%*	*45.43%*	*49.61%*	*100.00%*	*4.96%*
	0.00%	0.14%	0.01%	0.01%	0.05%	1.12%	0.09%	0.03%
Total	1,625	9,519	39,105	20,835	340,073	16,929	428,086	71,084
	0.38%	**2.22%**	**9.13%**	**4.87%**	**79.44%**	**3.95%**	**100.00%**	**16.61%**
	0.38%	*2.22%*	*9.13%*	*4.87%*	*79.44%*	*3.95%*	*100.00%*	*16.61%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender
In FY2008 more females (8,029,181; 63.84%) than males (4,406,583; 35.04%) were enrolled in aggregate extramural research protocols.
More minority females (2,263,551; 61.25%) than minority males (1,414,608; 38.28%) were enrolled in aggregate extramural research protocols.

Race
Approximately 29.38% (3,695,588) of participants in aggregate extramural research (12,576,868 total) were classified as U.S. minorities.
Largest identified racial group was White at 79.44% following the 1977 OMB standards and 64.71% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 9.13% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 13.10% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.38%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.36%.

Ethnicity
8.31% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 45.55% (2nd largest category is Unknown/Other at 33.93%)
Smallest identified racial group was Hawaiian/Pacific Islanders at 0.23%
Of the 1,009,336 participants, 61.49% were women and 37.85% were men.
4.87% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

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

		Domestic				Foreign			
8A. PROTOCOLS REPORTED	**Total All Clinical Studies**	**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
Number of Protocols reporting females only	1,356	1,069	78.8%	131	9.7%	149	11.0%	7	0.5%
%	8.1%	7.8%		7.0%		14.8%		6.7%	
Number of Protocols reporting males only	624	434	69.6%	102	16.3%	85	13.6%	3	0.5%
%	3.7%	3.2%		5.5%		8.4%		2.9%	
Number of Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)	9,191	7,134	77.6%	1,399	15.2%	573	6.2%	85	0.9%
%	55.1%	52.0%		75.3%		57.0%		81.0%	
Total Number of Protocols with Enrollment	**11,171**	**8,637**	77.3%	**1,632**	14.6%	**807**	7.2%	**95**	0.9%
%	66.9%	63%		87.8%		80.2%		90.5%	
Number of Protocols with zero enrollment. Enrollment data has not yet been submitted.	5,518	5,082	92.1%	227	4.1%	199	3.6%	10	0.2%
%	33.1%	37.0%		12.2%		19.8%		9.5%	
Total Number of Protocols	**16,689**	**13,719**	82.2%	**1,859**	11.1%	**1,006**	6.0%	**105**	0.6%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

		Domestic				Foreign			
8B. ENROLLMENT REPORTED	**Total All Clinical Studies**	**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
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%
%	25.2%	28.7%		6.6%		6.2%		32.0%	
In Protocols reporting males only	396,076	338,422	85.4%	9,472	2.4%	22,741	5.7%	25,441	6.4%
%	2.1%	2.2%		0.4%		3.5%		4.8%	
In Protocols excluding female-only and male-only enrollment protocols	13,912,569	10,747,866	77.3%	2,247,994	16.2%	578,244	4.2%	338,465	2.4%
%	72.7%	69.1%		93.0%		90.2%		63.2%	
Enrollment Totals for all studies	**19,138,738**	**15,546,350**	81.2%	**2,416,529**	12.6%	**640,715**	3.3%	**535,144**	2.8%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

		Domestic				Foreign			
8C. MINORITY ENROLLMENT REPORTED		**Extramural**	**%**	**Intramural**	**%**	**Extramural**	**%**	**Intramural**	**%**
Minority Totals for all studies	**5,783,543**	**4,419,314**	76.4%	**579,285**	10.0%	**499,919**	8.6%	**285,025**	4.9%
% Minority enrollment	30.2%	28.4%		24.0%		78.0%		53.3%	

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

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data: **9,444**

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

Number of Protocols with Enrollment Data: **8,993**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	91,643	1,090,555	1,073,690	29,381	6,939,461	108,399	728,852	10,061,981	8,658,138	728,314	675,529	10,061,981
	0.57%	**6.83%**	**6.73%**	**0.18%**	**43.48%**	**0.68%**	**4.57%**	**63.05%**	**54.25%**	**4.56%**	**4.23%**	**63.05%**
	0.91%	*10.84%*	*10.67%*	*0.29%*	*68.97%*	*1.08%*	*7.24%*	*100.00%*	*86.05%*	*7.24%*	*6.71%*	*100.00%*
	68.59%	69.82%	53.28%	60.09%	62.98%	63.37%	72.24%	63.05%	62.89%	61.08%	67.56%	63.05%
Male	41,411	469,956	933,867	19,392	4,072,005	61,291	215,172	5,813,094	5,093,038	459,455	260,601	5,813,094
	0.26%	**2.94%**	**5.85%**	**0.12%**	**25.52%**	**0.38%**	1.35%	**36.43%**	**31.91%**	**2.88%**	**1.63%**	**36.43%**
	0.71%	*8.08%*	*16.06%*	*0.33%*	*70.05%*	*1.05%*	3.70%	*100.00%*	*87.61%*	*7.90%*	*4.48%*	*100.00%*
	30.99%	30.09%	46.34%	39.66%	36.95%	35.83%	21.33%	36.43%	36.99%	38.53%	26.06%	36.43%
Unknown	553	1,387	7,798	123	7,831	1,358	64,951	84,001	15,669	4,596	63,736	84,001
	0.00%	**0.01%**	**0.05%**	0.00%	**0.05%**	**0.01%**	***0.41%***	**0.53%**	**0.10%**	**0.03%**	**0.40%**	**0.53%**
	0.66%	*1.65%*	*9.28%*	0.15%	*9.32%*	*1.62%*	*77.32%*	*100.00%*	*18.65%*	*5.47%*	*75.88%*	*100.00%*
	0.41%	0.09%	0.39%	0.25%	0.07%	0.79%	6.44%	0.53%	0.11%	0.39%	6.37%	0.53%
Total	133,607	1,561,898	2,015,355	48,896	11,019,297	171,048	1,008,975	15,959,076	13,766,845	1,192,365	999,866	15,959,076
	0.84%	**9.79%**	**12.63%**	**0.31%**	**69.05%**	**1.07%**	**6.32%**	**100.00%**	**86.26%**	**7.47%**	**6.27%**	**100.00%**
	0.84%	*9.79%*	*12.63%*	*0.31%*	*69.05%*	*1.07%*	*6.32%*	*100.00%*	*86.26%*	*7.47%*	*6.27%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	22,861	28,987	29,538	1,701	427,774	33,373	184,098	728,332	3,005,540
%	**1.92%**	**2.43%**	**2.48%**	**0.14%**	**35.87%**	**2.80%**	**15.44%**	**61.07%**	**18.83%**
	3.14%	*3.98%*	*4.06%*	*0.23%*	*58.73%*	*4.58%*	*25.28%*	*100.00%*	*29.87%*
	58.60%	54.22%	33.76%	56.53%	63.93%	57.90%	65.09%	61.07%	61.55%
Male	15,986	24,346	57,394	1270	240,495	24,228	95,902	459,621	1,862,314
%	**1.34%**	**2.04%**	**4.81%**	**0.11%**	**20.17%**	**2.03%**	**8.04%**	**38.54%**	**11.67%**
	3.48%	*5.30%*	*12.49%*	*0.28%*	*52.32%*	*5.27%*	*20.87%*	*100.00%*	*32.04%*
	40.97%	45.54%	65.59%	42.21%	35.94%	42.03%	33.91%	38.54%	38.14%
Unknown	168	129	566	38	820	39	2,836	4,596	14,875
%	**0.01%**	**0.01%**	**0.05%**	**0.00%**	**0.07%**	**0.00%**	**0.24%**	**0.39%**	**0.09%**
	3.66%	*2.81%*	*12.32%*	*0.83%*	*17.84%*	*0.85%*	*61.71%*	*100.00%*	*17.71%*
	0.43%	0.24%	0.65%	1.26%	0.12%	0.07%	1.00%	0.39%	0.30%
TOTAL	39,015	53,462	87,498	3,009	669,089	57,640	282,836	1,192,549	4,882,729
	3.27%	**4.48%**	**7.34%**	**0.25%**	**56.11%**	**4.83%**	**23.72%**	**100.00%**	**30.60%**
	3.27%	*4.48%*	*7.34%*	*0.25%*	*56.11%*	*4.83%*	*23.72%*	*100.00%*	*30.60%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 9C

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

Number of Protocols with Enrollment Data:	451

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

Legend

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

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

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

Table 10. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

10A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**3,596,589**	**1,313,179**		**36.51%**
%	**45.61%**	**48.81%**		
Males	**4,147,836**	**1,359,572**		**32.78%**
%	**52.60%**	**50.54%**		
Unknown	**141,240**	**17,453**		**12.36%**
%	**1.79%**	**0.65%**		
TOTAL	**7,885,665**	**2,690,204**	**34.12%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**7,736**

10B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **7,361**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	35,360	314,994	558,191	23,664	2,239,935	73,443	278,062	3,523,649	2,930,462	373,580	219,608	3,523,650
	0.46%	**4.07%**	**7.22%**	**0.31%**	**28.96%**	**0.95%**	**3.60%**	**45.56%**	**37.89%**	**4.83%**	**2.84%**	**45.56%**
	1.00%	*8.94%*	*15.84%*	*0.67%*	*63.57%*	*2.08%*	*7.89%*	*100.00%*	*83.17%*	*10.60%*	*6.23%*	*100.00%*
	51.40%	52.75%	44.55%	57.43%	44.81%	54.25%	43.49%	45.56%	46.03%	49.56%	35.80%	45.56%
Male	32,920	280,625	686,904	17,335	2,750,884	60,495	240,319	4,069,482	3,420,952	373,562	274,968	4,069,482
	0.43%	**3.63%**	**8.88%**	**0.22%**	**35.57%**	**0.78%**	3.11%	**52.62%**	**44.23%**	**4.83%**	**3.56%**	**52.62%**
	0.81%	*6.90%*	*16.88%*	*0.43%*	*67.60%*	*1.49%*	5.91%	*100.00%*	*84.06%*	*9.18%*	*6.76%*	*100.00%*
	47.85%	47.00%	54.82%	42.07%	55.03%	44.69%	37.59%	52.62%	53.73%	49.56%	44.83%	52.62%
Unknown	517	1,479	7,828	204	8,472	1,435	120,922	140,857	15,360	6,669	118,828	140,857
	0.01%	**0.02%**	**0.10%**	0.00%	**0.11%**	**0.02%**	***1.56%***	**1.82%**	**0.20%**	**0.09%**	**1.54%**	**1.82%**
	0.37%	*1.05%*	*5.56%*	0.14%	*6.01%*	*1.02%*	*85.85%*	*100.00%*	*10.90%*	*4.73%*	*84.36%*	*100.00%*
	0.75%	0.25%	0.62%	0.50%	0.17%	1.06%	18.91%	1.82%	0.24%	0.88%	19.37%	1.82%
Total	68,797	597,098	1,252,923	41,203	4,999,291	135,373	639,303	7,733,988	6,366,774	753,811	613,404	7,733,989
	0.89%	**7.72%**	**16.20%**	**0.53%**	**64.64%**	**1.75%**	**8.27%**	**100.00%**	**82.32%**	**9.75%**	**7.93%**	**100.00%**
	0.89%	*7.72%*	*16.20%*	*0.53%*	*64.64%*	*1.75%*	*8.27%*	*100.00%*	*82.32%*	*9.75%*	*7.93%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	14,926	14,360	22,744	1,020	155,074	26,040	139,416	373,580	1,300,142
	1.98%	**1.90%**	**3.02%**	**0.14%**	**20.57%**	**3.45%**	**18.49%**	**49.56%**	**16.81%**
	4.00%	*3.84%*	*6.09%*	*0.27%*	*41.51%*	*6.97%*	*37.32%*	*100.00%*	*36.90%*
	49.29%	50.07%	29.29%	51.26%	52.32%	54.91%	51.37%	49.56%	48.82%
Male	15,188	14,201	54,648	933	140,538	21,269	126,785	373,562	1,345,602
	2.01%	**1.88%**	**7.25%**	**0.12%**	**18.64%**	**2.82%**	**16.82%**	**49.56%**	**17.40%**
	4.07%	*3.80%*	*14.63%*	*0.25%*	*37.62%*	*5.69%*	*33.94%*	*100.00%*	*33.07%*
	50.15%	49.52%	70.38%	46.88%	47.42%	44.85%	46.72%	49.56%	50.53%
Unknown	171	116	260	37	778	114	5,193	6,669	17,434
	0.02%	**0.02%**	**0.03%**	**0.00%**	**0.10%**	**0.02%**	**0.69%**	**0.88%**	**0.23%**
	2.56%	*1.74%*	*3.90%*	*0.55%*	*11.67%*	*1.71%*	*77.87%*	*100.00%*	*12.38%*
	0.56%	0.40%	0.33%	1.86%	0.26%	0.24%	1.91%	0.88%	0.65%
TOTAL	30,285	28,677	77,652	1,990	296,390	47,423	271,394	753,811	2,663,178
	4.02%	**3.80%**	**10.30%**	**0.26%**	**39.32%**	**6.29%**	**36.00%**	**100.00%**	**34.43%**
	4.02%	*3.80%*	*10.30%*	*0.26%*	*39.32%*	*6.29%*	*36.00%*	*100.00%*	*34.43%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 10

Number of Protocols with Enrollment Data: **375**

10C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	237	1,679	6,568	4,553	53,370	6,533	72,940	13,037
	0.16%	**1.11%**	**4.33%**	**3.00%**	**35.19%**	**4.31%**	**48.09%**	**8.60%**
	0.32%	*2.30%*	*9.00%*	*6.24%*	*73.17%*	*8.96%*	*100.00%*	*17.87%*
	50.21%	49.50%	49.51%	46.01%	47.71%	51.06%	48.09%	48.24%
Male	235	1,700	6,694	5,341	58,312	6,072	78,354	13,970
	0.15%	**1.12%**	**4.41%**	**3.52%**	**38.44%**	**4.00%**	**51.66%**	**9.21%**
	0.30%	*2.17%*	*8.54%*	*6.82%*	*74.42%*	*7.75%*	*100.00%*	*17.83%*
	49.79%	50.12%	50.46%	53.97%	52.13%	47.46%	51.66%	51.69%
Unknown	0	13	4	2	174	190	383	19
	0.000%	**0.01%**	**0.00%**	**0.00%**	**0.11%**	**0.13%**	**0.25%**	**0.01%**
	0.00%	*3.39%*	*1.04%*	*0.52%*	*45.43%*	*49.61%*	*100.00%*	*4.96%*
	0.00%	0.38%	0.03%	0.02%	0.16%	1.48%	0.25%	0.07%
Total	472	3,392	13,266	9,896	111,856	12,795	151,677	27,026
	0.31%	**2.24%**	**8.75%**	**6.52%**	**73.75%**	**8.44%**	**100.00%**	**17.82%**
	0.31%	*2.24%*	*8.75%*	*6.52%*	*73.75%*	*8.44%*	*100.00%*	*17.82%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

Excluding sex-specific studies, the number of males (4,147,836 or 52.60%) exceeded the number of females (3,596,589 or 45.61%) enrolled in Extramural Research Protocols.
Excluding sex-specific studies, the number of minority males (1,359,572 or 50.54%) exceeded the number of minority females (1,313,179 or 48.81%) enrolled in Extramural Research Protocols.

Race

Approximately 34.12% (2,690,204) of participants in aggregate Extramural Research Protocols (7,885,665 total) were classified as U.S. minorities.
Largest identified racial group was White at 73.75% following the 1977 OMB standards and 64.64% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 8.75% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 16.20% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.31%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.53%.

Ethnicity

9.75% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 39.32% (2nd largest category was Unknown/Other at 36.00%)
Smallest identified racial groups was Hawaiian/Pacific Islander at 0.26%.
Of the 753,811 participants, 49.56% were women and 49.56% were men.
6.52% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 11A. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male_Only and Female-Only Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	7,707

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

Number of Protocols with Enrollment Data: 7,404

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	44,382	433,527	816,068	26,622	4,011,827	75,247	226,437	5,634,110	4,980,970	449,485	203,655	5,634,110
	0.40%	3.87%	7.28%	0.24%	35.77%	0.67%	2.02%	50.23%	44.41%	4.01%	1.82%	50.23%
	0.79%	7.69%	14.48%	0.47%	71.21%	1.34%	4.02%	100.00%	88.41%	7.98%	3.61%	100.00%
	51.75%	52.20%	47.38%	57.97%	50.82%	55.27%	45.23%	50.23%	50.55%	49.79%	44.38%	50.23%
Male	40,828	395,569	898,353	19,179	3,875,190	59,547	209,270	5,497,936	4,857,833	448,637	191,466	5,497,936
	0.36%	3.53%	8.01%	0.17%	34.55%	0.53%	1.87%	49.02%	43.31%	4.00%	1.71%	49.02%
	0.74%	7.19%	16.34%	0.35%	70.48%	1.08%	3.81%	100.00%	88.36%	8.16%	3.48%	100.00%
	47.61%	47.63%	52.16%	41.76%	49.09%	43.74%	41.80%	49.02%	49.30%	49.70%	41.73%	49.02%
Unknown	553	1,387	7,798	123	7,831	1,358	64,951	84,001	15,669	4,596	63,736	84,001
	0.00%	0.01%	0.07%	0.00%	0.07%	0.01%	0.58%	0.75%	0.14%	0.04%	0.57%	0.75%
	0.66%	1.65%	9.28%	0.15%	9.32%	1.62%	77.32%	100.00%	18.65%	5.47%	75.88%	100.00%
	0.64%	0.17%	0.45%	0.27%	0.10%	1.00%	12.97%	0.75%	0.16%	0.51%	13.89%	0.75%
Total	85,763	830,483	1,722,219	45,924	7,894,848	136,152	500,658	11,216,047	9,854,472	902,718	458,857	11,216,047
	0.76%	7.40%	15.35%	0.41%	70.39%	1.21%	4.46%	100.00%	87.86%	8.05%	4.09%	100.00%
	0.76%	7.40%	15.35%	0.41%	70.39%	1.21%	4.46%	100.00%	87.86%	8.05%	4.09%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	16,377	25,246	25,141	1,408	259,664	25,744	95,923	449,503	1,751,433
%	1.81%	2.80%	2.78%	0.16%	28.76%	2.85%	10.62%	49.78%	15.62%
	3.64%	5.62%	5.59%	0.31%	57.77%	5.73%	21.34%	100.00%	31.09%
	50.72%	50.80%	30.49%	52.13%	52.10%	54.81%	50.37%	49.78%	49.91%
Male	15,741	24,322	56,761	1255	237,869	21,183	91,672	448,803	1,743,017
%	1.74%	2.69%	6.29%	0.14%	26.34%	2.35%	10.15%	49.71%	15.54%
	3.51%	5.42%	12.65%	0.28%	53.00%	4.72%	20.43%	100.00%	31.70%
	48.75%	48.94%	68.83%	46.46%	47.73%	45.10%	48.14%	49.71%	49.67%
Unknown	168	129	566	38	820	39	2,836	4,596	14,875
%	0.02%	0.01%	0.06%	0.00%	0.09%	0.00%	0.31%	0.51%	0.13%
	3.66%	2.81%	12.32%	0.83%	17.84%	0.85%	61.71%	100.00%	17.71%
	0.52%	0.26%	0.69%	1.41%	0.16%	0.08%	1.49%	0.51%	0.42%
TOTAL	32,286	49,697	82,468	2,701	498,353	46,966	190,431	902,902	3,509,325
	3.58%	5.50%	9.13%	0.30%	55.19%	5.20%	21.09%	100.00%	31.29%
	3.58%	5.50%	9.13%	0.30%	55.19%	5.20%	21.09%	100.00%	31.29%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 11C

Number of Protocols with Enrollment Data: 303

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

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

Legend

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

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

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

Table 12. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2008: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

			Domestic				Foreign			
12A. PROTOCOLS REPORTED		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Protocols reporting female only		126	111	88.1%	4	3.2%	10	7.9%	1	0.8%
%		17.1%	17.5%		11.4%		16.7%		25.0%	
Protocols reporting male only		42	40	95.2%	0	0.0%	2	4.8%	0	0.0%
%		5.7%	6.3%		0.0%		3.3%		0.0%	
Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)		471	401	85.1%	29	6.2%	38	8.1%	3	0.6%
%		64.1%	63.1%		82.9%		63.3%		75.0%	
Total Number of Protocols with Enrollment		**639**	**552**	86.4%	**33**	5.2%	**50**	7.8%	**4**	0.6%
%		86.9%	87%		94.3%		83.3%		100.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.		96	84	87.5%	2	2.1%	10	10.4%	0	0.0%
%		13.1%	13.2%		5.7%		16.7%		0.0%	
Total Number of Phase III Protocols		**735**	**636**	86.5%	**35**	4.8%	**60**	8.2%	**4**	0.5%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
12B. ENROLLMENT REPORTED		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Protocols reporting female only		219,673	199,371	90.8%	9	0.0%	12,827	5.8%	7,466	3.4%
%		27.7%	34.1%		0.1%		6.7%		71.4%	
Protocols reporting male only		79,613	76,378	95.9%	159	0.2%	3,076	3.9%	0	0.0%
%		10.0%	13.1%		2.6%		1.6%		0.0%	
Protocols excluding female-only and men-only enrollment protocols		493,292	309,274	62.7%	5,914	1.2%	175,108	35.5%	2,996	0.6%
%		62.2%	52.9%		97.2%		91.7%		28.6%	
Total Subjects Enrolled		**792,578**	**585,023**	73.8%	**6,082**	0.77%	**191,011**	24.10%	**10,462**	1.3%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
12C. MINORITY ENROLLMENT REPORTED**		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Minority Total for all Phase III studies		**308,433**	**117,869**	38.2%	**1,713**	0.6%	**181,188**	58.7%	**7,663**	2.5%
%		38.9%	20.1%		28.2%		94.9%		73.2%	

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

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

Table 13. Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

13A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**444,079**	**161,091**		**36.28%**
%	**57.22%**	**53.87%**		
Males	**314,948**	**137,069**		**43.52%**
%	**40.58%**	**45.84%**		
Unknown	**17,007**	**882**		**5.19%**
%	**2.19%**	**0.29%**		
TOTAL	**776,034**	**299,042**	**38.53%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**605**

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

Number of Protocols with Enrollment Data: 452

	Total of All Subjects by Race								**Total of All Subjects by Ethnicity**			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown/ Not Reported**	**Total**
Female	7,618	49,108	54,738	336	151,809	6,536	13,129	283,274	243,922	29,653	9,699	283,274
	1.39%	**8.98%**	**10.01%**	**0.06%**	**27.77%**	**1.20%**	**2.40%**	**51.82%**	**44.62%**	**5.42%**	**1.77%**	**51.82%**
	2.69%	*17.34%*	*19.32%*	*0.12%*	*53.59%*	*2.31%*	*4.63%*	*100.00%*	*86.11%*	*10.47%*	*3.42%*	*100.00%*
	50.79%	51.60%	53.61%	52.58%	54.22%	53.87%	31.52%	51.82%	53.22%	52.25%	30.68%	51.82%
Male	7,328	45,963	47,069	299	126,943	5,472	13,366	246,440	212,880	26,676	6,884	246,440
	1.34%	**8.41%**	**8.61%**	**0.05%**	**23.22%**	**1.00%**	2.44%	**45.08%**	**38.94%**	**4.88%**	**1.26%**	**45.08%**
	2.97%	*18.65%*	*19.10%*	*0.12%*	*51.51%*	*2.22%*	5.42%	*100.00%*	*86.38%*	*10.82%*	*2.79%*	*100.00%*
	48.86%	48.29%	46.10%	46.79%	45.34%	45.10%	32.09%	45.08%	46.45%	47.00%	21.78%	45.08%
Unknown	53	103	294	4	1,257	124	15,152	16,987	1,536	425	15,026	16,987
	0.01%	**0.02%**	**0.05%**	0.00%	**0.23%**	**0.02%**	*2.77%*	**3.11%**	**0.28%**	**0.08%**	**2.75%**	**3.11%**
	0.31%	*0.61%*	*1.73%*	0.02%	*7.40%*	*0.73%*	*89.20%*	*100.00%*	*9.04%*	*2.50%*	*88.46%*	*100.00%*
	0.35%	0.11%	0.29%	0.63%	0.45%	1.02%	36.38%	3.11%	0.34%	0.75%	47.54%	3.11%
Total	14,999	95,174	102,101	639	280,009	12,132	41,647	546,701	458,338	56,754	31,609	546,701
	2.74%	**17.41%**	**18.68%**	**0.12%**	**51.22%**	**2.22%**	**7.62%**	**100.00%**	**83.84%**	**10.38%**	**5.78%**	**100.00%**
	2.74%	*17.41%*	*18.68%*	*0.12%*	*51.22%*	*2.22%*	*7.62%*	*100.00%*	*83.84%*	*10.38%*	*5.78%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	6524	95	337	65	12607	3170	6855	29,653	137,798
	11.50%	**0.17%**	**0.59%**	**0.11%**	**22.21%**	**5.59%**	**12.08%**	**52.25%**	**25.21%**
	22.00%	*0.32%*	*1.14%*	*0.22%*	*42.52%*	*10.69%*	*23.12%*	*100.00%*	*48.64%*
	49.97%	41.67%	47.13%	53.28%	56.32%	56.01%	46.98%	52.25%	52.59%
Male	6,489	126	370	54	9,665	2428	7544	26,676	123,340
	11.43%	**0.22%**	**0.65%**	**0.10%**	**17.03%**	**4.28%**	**13.29%**	**47.00%**	**22.56%**
	24.33%	*0.47%*	*1.39%*	*0.20%*	*36.23%*	*9.10%*	*28.28%*	*100.00%*	*50.05%*
	49.71%	55.26%	51.75%	44.26%	43.18%	42.90%	51.70%	47.00%	47.07%
Unknown	42	7	8	3	111	62	192	425	881
	0.07%	**0.01%**	**0.01%**	**0.01%**	**0.20%**	**0.11%**	**0.34%**	**0.75%**	**0.16%**
	9.88%	*1.65%*	*1.88%*	*0.71%*	*26.12%*	*14.59%*	*45.18%*	*100.00%*	*5.19%*
	0.32%	3.07%	1.12%	2.46%	0.50%	1.10%	1.32%	0.75%	0.34%
TOTAL	13,055	228	715	122	22,383	5,660	14,591	56,754	262,019
	23.00%	**0.40%**	**1.26%**	**0.21%**	**39.44%**	**9.97%**	**25.71%**	**100.00%**	**47.93%**
	23.00%	*0.40%*	*1.26%*	*0.21%*	*39.44%*	*9.97%*	*25.71%*	*100.00%*	*47.93%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 13

Number of Protocols with Enrollment Data: **153**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	652	3,449	13,516	5,676	134,866	2,646	160,805	23,293
	0.28%	**1.50%**	**5.89%**	**2.48%**	**58.81%**	**1.15%**	**70.12%**	**10.16%**
	0.41%	*2.14%*	*8.41%*	*3.53%*	*83.87%*	*1.65%*	*100.00%*	*14.49%*
	72.85%	77.02%	61.21%	59.33%	71.71%	62.35%	70.12%	62.91%
Male	243	1,029	8,566	3,891	53,192	1,587	68,508	13,729
	0.11%	**0.45%**	**3.74%**	**1.70%**	**23.19%**	**0.69%**	**29.87%**	**5.99%**
	0.35%	*1.50%*	*12.50%*	*5.68%*	*77.64%*	*2.32%*	*100.00%*	*20.04%*
	27.15%	22.98%	38.79%	40.67%	28.28%	37.39%	29.87%	37.08%
Unknown	0	0	1	0	8	11	20	1
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*5.00%*	*0.00%*	*40.00%*	*55.00%*	*100.00%*	*5.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.26%	0.01%	0.00%
Total	895	4,478	22,083	9,567	188,066	4,244	229,333	37,023
	0.39%	**1.95%**	**9.63%**	**4.17%**	**82.01%**	**1.85%**	**100.00%**	**16.14%**
	0.39%	*1.95%*	*9.63%*	*4.17%*	*82.01%*	*1.85%*	*100.00%*	*16.14%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

More females (444,079 or 57.22%) than males (314,948 or 40.58%) were enrolled in aggregate Phase III Extramural Research Protocols.
More minority females (161,091 or 53.87%) than males (137,069 or 45.84%) were enrolled in aggregate Phase III Extramural Research Protocols.

Race

Approximately 38.53% (299,042) of participants in aggregate Phase III Extramural Research (776,034 total) were classified as U.S. minorities.
Largest identified racial group was White at 82.01% following the 1977 OMB standards and 51.22% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 9.63% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 18.68% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.39%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.12%.

Ethnicity

About 10.38% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 39.44% (2nd largest category was Unknown/ Other at 25.71%)
Smallest identified racial group was Hawaiian/Pacific Islander at 0.21%.
Of the 56,754 participants, 52.25% were women and 47.00% were men.
About 4.17% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

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

			Domestic				Foreign			
14A. PROTOCOLS REPORTED		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Protocols reporting female only		151	94	62.3%	2	1.3%	54	35.8%	1	0.8%
%		22.8%	21.1%		5.1%		31.2%		25.0%	
Protocols reporting male only		48	25	52.1%	2	4.2%	21	43.8%	0	0.0%
%		7.3%	5.6%		5.1%		12.1%		0.0%	
Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)		431	304	70.5%	30	7.0%	94	21.8%	3	0.7%
%		65.1%	68.2%		76.9%		54.3%		75.0%	
Total Number of Protocols with Enrollment		**630**	**423**	67.1%	**34**	5.4%	**169**	26.8%	**4**	0.6%
%		95.2%	95%		87.2%		97.7%		100.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.		32	23	71.9%	5	15.6%	4	12.5%	0	0.0%
%		4.8%	5.2%		12.8%		2.3%		0.0%	
Total Number of Phase III Protocols		**662**	**446**	67.4%	**39**	5.9%	**173**	26.1%	**4**	0.6%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
14B. ENROLLMENT REPORTED		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Protocols reporting female only		141,892	123,187	86.8%	5	0.0%	11,234	7.9%	7,466	5.3%
%		21.8%	22.7%		0.1%		12.1%		71.3%	
Protocols reporting male only		65,516	59,488	90.8%	155	0.2%	5,873	9.0%	0	0.0%
%		10.0%	11.0%		2.6%		6.3%		0.0%	
Protocols excluding female-only and men-only enrollment protocols		444,892	360,025	80.9%	5,840	1.3%	76,018	17.1%	3,009	0.7%
%		68.2%	66.3%		97.3%		81.6%		28.7%	
Total Subjects Enrolled		**652,300**	**542,700**	83.2%	**6,000**	0.92%	**93,125**	14.28%	**10,475**	1.6%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
14C. MINORITY ENROLLMENT REPORTED**		**Total of Phase III Clinical Trials***	**Extra-mural**	**%**	**Intra-mural**	**%**	**Extra-mural**	**%**	**Intra-mural**	**%**
Minority Total for all Phase III studies		**291,949**	**210,317**	72.0%	**1,567**	0.5%	**72,389**	24.8%	**7,676**	2.6%
%		44.8%	38.8%		26.1%		77.7%		73.3%	

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

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	**592**

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

Number of Protocols with Enrollment Data: 407

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	9,746	47,842	61,229	438	106,737	2,281	14,361	242,634	209,663	26,804	6,167	242,634
	2.06%	**10.11%**	**12.94%**	**0.09%**	**22.56%**	**0.48%**	**3.04%**	**51.28%**	**44.31%**	**5.67%**	**1.30%**	**51.28%**
	4.02%	*19.72%*	*25.24%*	*0.18%*	*43.99%*	*0.94%*	*5.92%*	*100.00%*	*86.41%*	*11.05%*	*2.54%*	*100.00%*
	56.23%	51.53%	53.13%	51.05%	56.50%	48.82%	26.96%	51.28%	53.85%	60.18%	15.72%	51.28%
Male	7,528	44,893	53,855	416	80,993	2,332	10,134	200,151	178,242	17,354	4,555	200,151
	1.59%	**9.49%**	**11.38%**	**0.09%**	**17.12%**	**0.49%**	2.14%	**42.30%**	**37.67%**	**3.67%**	**0.96%**	**42.30%**
	3.76%	*22.43%*	*26.91%*	*0.21%*	*40.47%*	*1.17%*	5.06%	*100.00%*	*89.05%*	*8.67%*	*2.28%*	*100.00%*
	43.43%	48.35%	46.73%	48.48%	42.88%	49.91%	19.02%	42.30%	45.78%	38.97%	11.61%	42.30%
Unknown	59	108	168	4	1,169	59	28,776	30,343	1,449	379	28,515	30,343
	0.01%	**0.02%**	**0.04%**	0.00%	**0.25%**	**0.01%**	***6.08%***	**6.41%**	**0.31%**	**0.08%**	**6.03%**	**6.41%**
	0.19%	*0.36%*	*0.55%*	0.01%	*3.85%*	*0.19%*	*94.84%*	*100.00%*	*4.78%*	*1.25%*	*93.98%*	*100.00%*
	0.34%	0.12%	0.15%	0.47%	0.62%	1.26%	54.02%	6.41%	0.37%	0.85%	72.67%	6.41%
Total	17,333	92,843	115,252	858	188,899	4,672	53,271	473,128	389,354	44,537	39,237	473,128
	3.66%	**19.62%**	**24.36%**	**0.18%**	**39.93%**	**0.99%**	**11.26%**	**100.00%**	**82.29%**	**9.41%**	**8.29%**	**100.00%**
	3.66%	*19.62%*	*24.36%*	*0.18%*	*39.93%*	*0.99%*	*11.26%*	*100.00%*	*82.29%*	*9.41%*	*8.29%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	8,728	138	488	99	7,263	431	9,657	26,804	138,456
%	**19.60%**	**0.31%**	**1.10%**	**0.22%**	**16.31%**	**0.97%**	**21.68%**	**60.18%**	**29.26%**
	32.56%	*0.51%*	*1.82%*	*0.37%*	*27.10%*	*1.61%*	*36.03%*	*100.00%*	*57.06%*
	57.00%	39.32%	52.08%	50.00%	63.24%	44.71%	63.15%	60.18%	53.72%
Male	6,543	203	439	95	4,159	521	5,394	17,354	118,577
%	**14.69%**	**0.46%**	**0.99%**	**0.21%**	**9.34%**	**1.17%**	**12.11%**	**38.97%**	**25.06%**
	37.70%	*1.17%*	*2.53%*	*0.55%*	*23.97%*	*3.00%*	*31.08%*	*100.00%*	*59.24%*
	42.73%	57.83%	46.85%	47.98%	36.22%	54.05%	35.28%	38.97%	46.01%
Unknown	41	10	10	4	62	12	240	379	700
%	**0.09%**	**0.02%**	**0.02%**	**0.01%**	**0.14%**	**0.03%**	**0.54%**	**0.85%**	**0.15%**
	10.82%	*2.64%*	*2.64%*	*1.06%*	*16.36%*	*3.17%*	*63.32%*	*100.00%*	*2.31%*
	0.27%	2.85%	1.07%	2.02%	0.54%	1.24%	1.57%	0.85%	0.27%
TOTAL	15,312	351	937	198	11,484	964	15,291	44,537	257,733
	34.38%	**0.79%**	**2.10%**	**0.44%**	**25.79%**	**2.16%**	**34.33%**	**100.00%**	**54.47%**
	34.38%	*0.79%*	*2.10%*	*0.44%*	*25.79%*	*2.16%*	*34.33%*	*100.00%*	*54.47%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 15C

Number of Protocols with Enrollment Data: **185**

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

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

Legend

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

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

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

Table 16. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

16A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	1,214,079	349,293		28.77%
%	42.82%	48.43%		
Males	1,585,861	371,373		23.42%
%	55.93%	51.50%		
Unknown	35,546	515		1.45%
%	1.25%	0.07%		
TOTAL	2,835,486	721,181	25.43%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**1,664**

16B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: **1,251**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown/ Not Reported**	**Total**
Female	10,523	166,051	61,501	3,985	775,883	11,344	84,101	1,113,388	989,883	60,344	63,161	1,113,388
	0.40%	**6.30%**	**2.33%**	**0.15%**	**29.42%**	**0.43%**	**3.19%**	**42.21%**	**37.53%**	**2.29%**	**2.39%**	**42.21%**
	0.95%	*14.91%*	*5.52%*	*0.36%*	*69.69%*	*1.02%*	*7.55%*	*100.00%*	*88.91%*	*5.42%*	*5.67%*	*100.00%*
	49.31%	64.25%	24.81%	87.43%	43.31%	70.13%	28.24%	42.21%	44.00%	56.20%	22.54%	42.21%
Male	10,786	91,976	186,322	573	1,012,698	4,832	181,472	1,488,659	1,256,314	47,010	185,335	1,488,659
	0.41%	**3.49%**	**7.06%**	**0.02%**	**38.40%**	**0.18%**	6.88%	**56.44%**	**47.63%**	**1.78%**	**7.03%**	**56.44%**
	0.72%	*6.18%*	*12.52%*	*0.04%*	*68.03%*	*0.32%*	12.19%	*100.00%*	*84.39%*	*3.16%*	*12.45%*	*100.00%*
	50.55%	35.59%	75.17%	12.57%	56.53%	29.87%	60.94%	56.44%	55.84%	43.78%	66.14%	56.44%
Unknown	30	428	48	0	2,800	0	32,217	35,523	3768	17	31,738	35,523
	0.00%	**0.02%**	**0.00%**	0.00%	**0.11%**	**0.00%**	***1.22%***	**1.35%**	**0.14%**	**0.00%**	**1.20%**	**1.35%**
	0.08%	*1.20%*	*0.14%*	0.00%	*7.88%*	*0.00%*	*90.69%*	*100.00%*	*10.61%*	*0.05%*	*89.34%*	*100.00%*
	0.14%	0.17%	0.02%	0.00%	0.16%	0.00%	10.82%	1.35%	0.17%	0.02%	11.33%	1.35%
Total	21,339	258,455	247,871	4,558	1,791,381	16,176	297,790	2,637,570	2,249,965	107,371	280,234	2,637,570
	0.81%	**9.80%**	**9.40%**	**0.17%**	**67.92%**	**0.61%**	**11.29%**	**100.00%**	**85.30%**	**4.07%**	**10.62%**	**100.00%**
	0.81%	*9.80%*	*9.40%*	*0.17%*	*67.92%*	*0.61%*	*11.29%*	*100.00%*	*85.30%*	*4.07%*	*10.62%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	86	22	455	50	27,870	3,137	28,724	60,344	309,998
	0.08%	**0.02%**	**0.42%**	**0.05%**	**25.96%**	**2.92%**	**26.75%**	**56.20%**	**11.75%**
	0.14%	*0.04%*	*0.75%*	*0.08%*	*46.19%*	*5.20%*	*47.60%*	*100.00%*	*27.84%*
	58.90%	45.83%	14.45%	65.79%	47.41%	51.19%	73.59%	56.20%	47.97%
Male	52	26	2694	26	30,919	2,991	10,302	47,010	335,710
	0.05%	**0.02%**	**2.51%**	**0.02%**	**28.80%**	**2.79%**	**9.59%**	**43.78%**	**12.73%**
	0.11%	*0.06%*	*5.73%*	*0.06%*	*65.77%*	*6.36%*	*21.91%*	*100.00%*	*22.55%*
	35.62%	54.17%	85.55%	34.21%	52.59%	48.81%	26.39%	43.78%	51.95%
Unknown	8	0	0	0	0	0	9	17	515
	0.01%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.02%**	**0.02%**
	47.06%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*52.94%*	*100.00%*	*1.45%*
	5.48%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.02%	0.08%
TOTAL	146	48	3,149	76	58,789	6,128	39,035	107,371	646,223
	0.14%	**0.04%**	**2.93%**	**0.07%**	**54.75%**	**5.71%**	**36.36%**	**100.00%**	**24.50%**
	0.14%	*0.04%*	*2.93%*	*0.07%*	*54.75%*	*5.71%*	*36.36%*	*100.00%*	*24.50%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 16

Number of Protocols with Enrollment Data: **413**

16C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	150	3,531	31,362	4,252	59,909	1,487	100,691	39,295
	0.08%	**1.78%**	**15.85%**	**2.15%**	**30.27%**	**0.75%**	**50.88%**	**19.85%**
	0.15%	*3.51%*	*31.15%*	*4.22%*	*59.50%*	*1.48%*	*100.00%*	*39.03%*
	0.00%	52.85%	52.24%	53.50%	49.84%	53.94%	50.88%	52.42%
Male	141	3,150	28,676	3,696	60,287	1,252	97,202	35,663
	0.07%	**1.59%**	**14.49%**	**1.87%**	**30.46%**	**0.63%**	**49.11%**	**18.02%**
	0.15%	*3.24%*	*29.50%*	*3.80%*	*62.02%*	*1.29%*	*100.00%*	*36.69%*
	0.00%	47.15%	47.76%	46.50%	50.16%	45.41%	49.11%	47.58%
Unknown	0	0	0	0	5	18	23	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.01%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*21.74%*	*78.26%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.65%	0.01%	0.00%
Total	291	6,681	60,038	7,948	120,201	2,757	197,916	74,958
	0.15%	**3.38%**	**30.34%**	**4.02%**	**60.73%**	**1.39%**	**100.00%**	**37.87%**
	0.15%	*3.38%*	*30.34%*	*4.02%*	*60.73%*	*1.39%*	*100.00%*	*37.87%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

More males (1,585,861 or 55.93%) than females (1,214,079 or 42.82%) were enrolled in aggregate Intramural Research Protocols.
More minority males (371,373 or 51.50%) than females (349,293 or 48.43%) were enrolled in aggregate Intramural Research Protocols.

Race

Approximately 25.43% (721,181) of participants in aggregate Intramural Research (2,835,486 total) were classified as U.S. minorities.
Largest identified racial group was White at 60.73% following the 1977 OMB standards and 67.92% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 30.34% following the 1977 OMB standards.
Largest identified racial minority group was Asian at 9.80% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.15%.
According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.17%.

Ethnicity

4.07% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was White at 54.75% (2nd largest category Unknown/Other at 36.36%).
Smallest identified racial group was Asian at 0.04%.
Of the 107,371 participants, 56.20% were women and 43.78% were men.
4.02% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 17. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	1,727

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

Number of Protocols with Enrollment Data: 1,335

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	9,820	176,141	72,500	654	740,001	78,852	90,893	1,168,861	967,503	61,626	139,732	1,168,861
	0.35%	**6.31%**	**2.60%**	**0.02%**	**26.52%**	**2.83%**	**3.26%**	**41.89%**	**34.68%**	**2.21%**	**5.01%**	**41.89%**
	0.84%	*15.07%*	*6.20%*	*0.06%*	*63.31%*	*6.75%*	*7.78%*	*100.00%*	*82.77%*	*5.27%*	*11.95%*	*100.00%*
	46.97%	63.21%	26.63%	45.32%	41.77%	51.61%	31.07%	41.89%	42.68%	55.73%	33.84%	41.89%
Male	11,064	102,131	195,873	789	1,020,111	73,920	172,687	1,576,575	1,283,484	48,930	244,161	1,576,575
	0.40%	**3.66%**	**7.02%**	**0.03%**	**36.56%**	**2.65%**	6.19%	**56.50%**	**46.00%**	**1.75%**	**8.75%**	**56.50%**
	0.70%	*6.48%*	*12.42%*	*0.05%*	*64.70%*	*4.69%*	10.95%	*100.00%*	*81.41%*	*3.10%*	*15.49%*	*100.00%*
	52.92%	36.65%	71.95%	54.68%	57.58%	48.38%	59.03%	56.50%	56.62%	44.25%	59.13%	56.50%
Unknown	24	369	3,849	0	11,536	19	28,963	44,760	15,715	23	29,022	44,760
	0.00%	**0.01%**	**0.14%**	0.00%	**0.41%**	**0.00%**	*1.04%*	**1.60%**	**0.56%**	**0.00%**	**1.04%**	**1.60%**
	0.05%	*0.82%*	*8.60%*	0.00%	*25.77%*	*0.04%*	*64.71%*	*100.00%*	*35.11%*	*0.05%*	*64.84%*	*100.00%*
	0.11%	0.13%	1.41%	0.00%	0.65%	0.01%	9.90%	1.60%	0.69%	0.02%	7.03%	1.60%
Total	20,908	278,641	272,222	1,443	1,771,648	152,791	292,543	2,790,196	2,266,702	110,579	412,915	2,790,196
	0.75%	**9.99%**	**9.76%**	**0.05%**	**63.50%**	**5.48%**	**10.48%**	**100.00%**	**81.24%**	**3.96%**	**14.80%**	**100.00%**
	0.75%	*9.99%*	*9.76%*	*0.05%*	*63.50%*	*5.48%*	*10.48%*	*100.00%*	*81.24%*	*3.96%*	*14.80%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	118	43	806	59	28,524	3,224	28,852	61,626	395,343
%	**0.11%**	**0.04%**	**0.73%**	**0.05%**	**25.80%**	**2.92%**	**26.09%**	**55.73%**	**14.17%**
	0.19%	*0.07%*	*1.31%*	*0.10%*	*46.29%*	*5.23%*	*46.82%*	*100.00%*	*33.82%*
	64.48%	51.19%	21.87%	62.77%	47.33%	51.22%	72.18%	55.73%	47.85%
Male	64	41	2,880	35	31,742	3,054	11,114	48,930	426,633
%	**0.06%**	**0.04%**	**2.60%**	**0.03%**	**28.71%**	**2.76%**	**10.05%**	**44.25%**	**15.29%**
	0.13%	*0.08%*	*5.89%*	*0.07%*	*64.87%*	*6.24%*	*22.71%*	*100.00%*	*27.06%*
	34.97%	48.81%	78.13%	37.23%	52.67%	48.52%	27.80%	44.25%	51.64%
Unknown	1	0	0	0	0	16	6	23	4,267
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.01%**	**0.02%**	**0.15%**
	4.35%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*69.57%*	*26.09%*	*100.00%*	*9.53%*
	0.55%	0.00%	0.00%	0.00%	0.00%	0.25%	0.02%	0.02%	0.52%
TOTAL	183	84	3,686	94	60,266	6,294	39,972	110,579	826,243
	0.17%	**0.08%**	**3.33%**	**0.09%**	**54.50%**	**5.69%**	**36.15%**	**100.00%**	**29.61%**
	0.17%	*0.08%*	*3.33%*	*0.09%*	*54.50%*	*5.69%*	*36.15%*	*100.00%*	*29.61%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 17

Number of Protocols with Enrollment Data: **392**

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

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

Legend

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

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

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

Table 18. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

18A. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**11,533**	**8,448**		**73.25%**
%	**69.71%**	**90.10%**		
Males	**4,784**	**915**		**19.13%**
%	**28.92%**	**9.76%**		
Unknown	**227**	**13**		**0.00%**
%	**1.37%**	**0.14%**		
TOTAL	**16,544**	**9,376**	**56.67%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **37**

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

Number of Protocols with Enrollment Data: **26**

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	6	36	629	77	695	2	8,933	10,378	1,361	7,527	1,490	10,378
	0.05%	**0.27%**	**4.72%**	**0.58%**	**5.21%**	**0.02%**	**67.00%**	**77.84%**	**10.21%**	**56.45%**	**11.18%**	**77.84%**
	0.06%	*0.35%*	*6.06%*	*0.74%*	*6.70%*	*0.02%*	*86.08%*	*100.00%*	*13.11%*	*72.53%*	*14.36%*	*100.00%*
	85.71%	29.51%	59.06%	100.00%	52.06%	50.00%	83.31%	77.84%	53.92%	99.08%	46.39%	77.84%
Male	1	86	423	0	640	2	1,576	2,728	1,150	70	1,508	2,728
	0.01%	**0.65%**	**3.17%**	**0.00%**	**4.80%**	**0.02%**	11.82%	**20.46%**	**8.63%**	**0.53%**	**11.31%**	**20.46%**
	0.04%	*3.15%*	*15.51%*	*0.00%*	*23.46%*	*0.07%*	57.77%	*100.00%*	*42.16%*	*2.57%*	*55.28%*	*100.00%*
	14.29%	70.49%	39.72%	0.00%	47.94%	50.00%	14.70%	20.46%	45.56%	0.92%	46.95%	20.46%
Unknown	0	0	13	0	0	0	214	227	13	0	214	227
	0.00%	**0.00%**	**0.10%**	0.00%	**0.00%**	**0.00%**	***0.00%***	**1.70%**	**0.10%**	**0.00%**	**1.61%**	**1.70%**
	0.00%	*0.00%*	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	1.22%	0.00%	0.00%	0.00%	2.00%	1.70%	0.52%	0.00%	6.66%	1.70%
Total	7	122	1,065	77	1,335	4	10,723	13,333	2,524	7,597	3,212	13,333
	0.05%	**0.92%**	**7.99%**	**0.58%**	**10.01%**	**0.03%**	**80.42%**	**100.00%**	**18.93%**	**56.98%**	**24.09%**	**100.00%**
	0.05%	*0.92%*	*7.99%*	*0.58%*	*10.01%*	*0.03%*	*80.42%*	*100.00%*	*18.93%*	*56.98%*	*24.09%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1	0	0	0	2	1	7,523	7,527	8,275
	0.01%	**0.00%**	**0.00%**	**0.00%**	**0.03%**	**0.01%**	**99.03%**	**99.08%**	**62.06%**
	0.01%	*0.00%*	*0.00%*	*0.00%*	*0.03%*	*0.01%*	*99.95%*	*100.00%*	*79.74%*
	100.00%	0.00%	0.00%	0.00%	66.67%	100.00%	99.09%	99.08%	93.29%
Male	0	0	0	0	1	0	69	70	582
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	**0.91%**	**0.92%**	**4.37%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*1.43%*	*0.00%*	*98.57%*	*100.00%*	*21.33%*
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	0.91%	0.92%	6.56%
Unknown	0	0	0	0	0	0	0	0	13
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.10%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.15%
TOTAL	1	0	0	0	3	1	7,592	7,597	8,870
	0.01%	**0.00%**	**0.00%**	**0.00%**	**0.04%**	**0.01%**	**99.93%**	**100.00%**	**66.53%**
	0.01%	*0.00%*	*0.00%*	*0.00%*	*0.04%*	*0.01%*	*99.93%*	*100.00%*	*66.53%*
	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 18

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

Number of Protocols with Enrollment Data: 11

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	2	23	121	27	977	5	1,155	173
	0.06%	**0.72%**	**3.77%**	**0.84%**	**30.43%**	**0.16%**	**35.97%**	**5.39%**
	0.17%	*1.99%*	*10.48%*	*2.34%*	*84.59%*	*0.43%*	*100.00%*	*14.98%*
	0.00%	35.94%	33.43%	36.00%	36.36%	27.78%	35.97%	34.19%
Male	3	41	241	48	1,710	13	2,056	333
	0.09%	**1.28%**	**7.51%**	**1.49%**	**53.25%**	**0.40%**	**64.03%**	**10.37%**
	0.15%	*1.99%*	*11.72%*	*2.33%*	*83.17%*	*0.63%*	*100.00%*	*16.20%*
	0.00%	64.06%	66.57%	64.00%	63.64%	72.22%	64.03%	65.81%
Unknown	0	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	5	64	362	75	2,687	18	3,211	506
	0.16%	**1.99%**	**11.27%**	**2.34%**	**83.68%**	**0.56%**	**100.00%**	**15.76%**
	0.16%	*1.99%*	*11.27%*	*2.34%*	*83.68%*	*0.56%*	*100.00%*	*15.76%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender
More females (11,533 or 69.71%) than males (4,784 or 28.92%) were enrolled in aggregate Intramural Phase III Research Protocols.
More minority females (8,448 or 90.10%) than males (915 or 9.76%) are enrolled in aggregate Intramural Phase III Research Protocols.

Race
Approximately 56.67% (9,376) of participants in aggregate Intramural Phase III Research (16,544 total) were classified as U.S. minorities.
Largest identified racial group was White at 83.68% following the 1977 OMB standards and Unknown/Other at 80.42% following the 1997 OMB standards.
Largest identified racial minority group was Black or African American at 11.27% following the 1977 OMB standards.
Largest identified racial minority group was Black or African American at 7.99% following the 1997 OMB standards.
According to the 1997 OMB standards, the smallest identified racial minority was More Than One Race at 0.03%.
According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.16%.

Ethnicity
56.98% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
For participants reporting ethnicity as Hispanic/Latino:
Largest identified racial group was Unknown/Other at 99.93% (2nd largest category is White at 0.04%).
Asian, Black or African American and Hawaiian/Pacific Islander all had 0.0%.
Of the 7,597 participants, 99.08% were women and 0.92% were men.
2.34% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 19. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	38

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

Number of Protocols with Enrollment Data: 27

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	129	6	594	0	368	2	9,169	10,268	1,282	7,553	1,433	10,268
	0.96%	**0.04%**	**4.42%**	**0.00%**	**2.74%**	**0.01%**	**68.25%**	**76.43%**	**9.54%**	**56.22%**	**10.67%**	**76.43%**
	1.26%	*0.06%*	*5.78%*	*0.00%*	*3.58%*	*0.02%*	*89.30%*	*100.00%*	*12.49%*	*73.56%*	*13.96%*	*100.00%*
	73.30%	24.00%	60.55%	0.00%	58.60%	50.00%	78.91%	76.43%	48.63%	98.27%	46.03%	76.43%
Male	47	19	374	1	260	2	2,451	3,154	1,341	133	1,680	3,154
	0.35%	**0.14%**	**2.78%**	**0.01%**	**1.94%**	**0.01%**	18.24%	**23.48%**	**9.98%**	**0.99%**	**12.50%**	**23.48%**
	1.49%	*0.60%*	*11.86%*	*0.03%*	*8.24%*	*0.06%*	77.71%	*100.00%*	*42.52%*	*4.22%*	*53.27%*	*100.00%*
	26.70%	76.00%	38.12%	100.00%	41.40%	50.00%	21.09%	23.48%	50.87%	1.73%	53.97%	23.48%
Unknown	0	0	13	0	0	0	0	13	13	0	0	13
	0.00%	**0.00%**	**0.10%**	0.00%	**0.00%**	**0.00%**	*0.00%*	**0.10%**	**0.10%**	**0.00%**	**0.00%**	**0.10%**
	0.00%	*0.00%*	*100.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	1.33%	0.00%	0.00%	0.00%	0.00%	0.10%	0.49%	0.00%	0.00%	0.10%
Total	176	25	981	1	628	4	11,620	13,435	2,636	7,686	3,113	13,435
	1.31%	**0.19%**	**7.30%**	**0.01%**	**4.67%**	**0.03%**	**86.49%**	**100.00%**	**19.62%**	**57.21%**	**23.17%**	**100.00%**
	1.31%	*0.19%*	*7.30%*	*0.01%*	*4.67%*	*0.03%*	*86.49%*	*100.00%*	*19.62%*	*57.21%*	*23.17%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female %	1	0	0	0	2	0	7,550	7,553	8,283
	0.01%	**0.00%**	**0.00%**	**0.00%**	**0.03%**	**0.00%**	**98.23%**	**98.27%**	**61.65%**
	0.01%	*0.00%*	*0.00%*	*0.00%*	*0.03%*	*0.00%*	*99.96%*	*100.00%*	*80.67%*
	100.00%	0.00%	0.00%	0.00%	66.67%	0.00%	98.28%	98.27%	93.36%
Male %	0	0	0	0	1	0	132	133	576
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	**1.72%**	**1.73%**	**4.29%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.75%*	*0.00%*	*99.25%*	*100.00%*	*18.26%*
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	1.72%	1.73%	6.49%
Unknown %	0	0	0	0	0	0	0	0	13
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.10%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.15%
TOTAL	1	0	0	0	3	0	7,682	7,686	8,872
	0.01%	**0.00%**	**0.00%**	**0.00%**	**0.04%**	**0.00%**	**99.95%**	**100.00%**	**66.04%**
	0.01%	*0.00%*	*0.00%*	*0.00%*	*0.04%*	*0.00%*	*99.95%*	*100.00%*	*66.04%*
	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 19

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

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

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

Legend

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

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

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

Table 20. NIH Fifteen Year Trends for Protocol and Enrollment Data: 1995-2009*

20A Part I. Fifteen Year Increases in Protocols and Enrollment Data

FY Reported	1995	2009	Relative Increase, 2009 / 1995
Total Protocols with Enrollment	**3,188**	**11,171**	**3.5**
Total Enrollment	**1,021,493**	**19,138,738**	**18.7**
Total Minorities	**374,433**	**5,783,543**	**15.4**
% of Minority	**36.7%**	**30.2%**	**0.8**

20A Part II. Fifteen Year Increases in Protocols and Enrollment Data: Foreign and Domestic

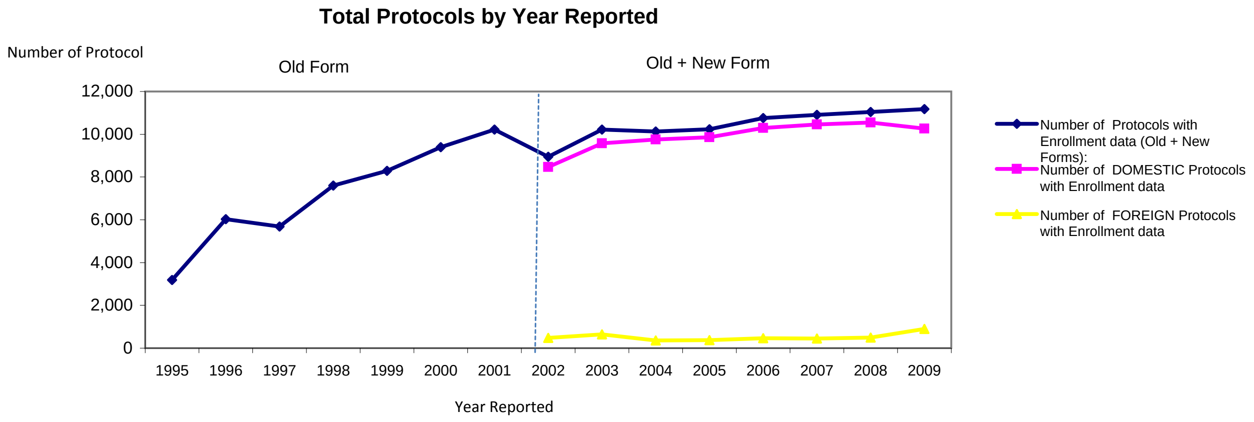
FY Reported	1995	2009	Relative Increase, 2009 / 1995
Total DOMESTIC Enrollment data	**10,192,401**	**17,962,879**	**1.8**
Total FOREIGN Enrollment	**946,083**	**1,175,859**	**1.2**

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

20B. Fifteen Year Summary of Total Number of Protocols Reported: FY 1995-2009

FY Reported	FY Funded	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols with Enrollment data	Number of FOREIGN Protocols with Enrollment data	Percent Domestic Protocols	Protocol Form*
1995	1994	3,188				Old
1996	1995	6,036				
1997	1996	5,692				
1998	1997	7,602				
1999	1998	8,285				
2000	1999	9,390				
2001	2000	10,212				
2002	2001	8,945	8,463	482	94.6%	Old + New
2003	2002	10,216	9,578	638	93.8%	
2004	2003	10,125	9,760	365	96.4%	
2005	2004	10,233	9,862	371	96.4%	
2006	2005	10,758	10,294	464	95.7%	
2007	2006	10,914	10,463	451	95.9%	
2008	2007	11,045	10,548	497	95.5%	
2009	2008	11,171	10,269	902	91.9%	

Table 20B Comments:



* Data have been reported using a combined race/ethnicity format (OLD FORM) since 1995. New protocols began reporting separate race and ethnicity data in FY2002 (NEW FORM). During 2002-2009, data have been reported using both Old and New Forms.

20C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2009

FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC Enrollment data	Percent DOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGN Enrollment
2002	2001	11,138,484	10,192,401	91.5%	946,083	8.5%
2003	2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%
2004	2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%
2005	2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%
2006	2005	14,830,930	11,425,701	77.0%	3,405,229	23.0%
2007	2006	17,448,458	16,180,588	92.7%	1,267,870	7.3%
2008	2007	15,412,355	14,134,627	91.7%	1,277,728	8.3%
2009	2008	19,138,738	17,962,879	93.9%	1,175,859	6.1%

Percent Comparison of Domestic and Foreign Enrolment

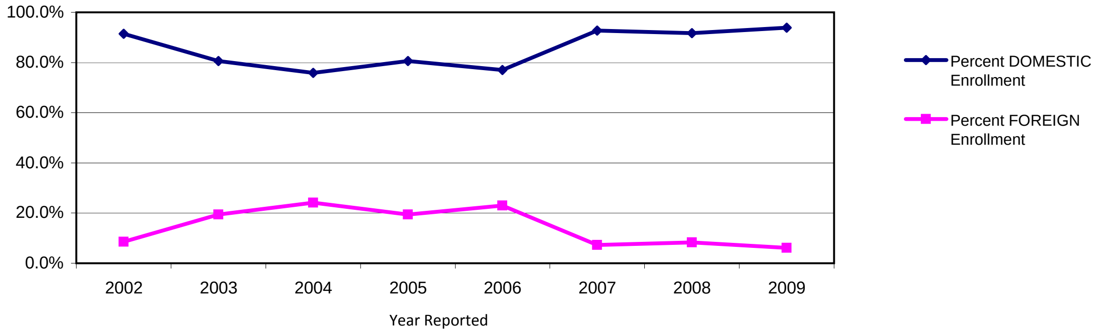
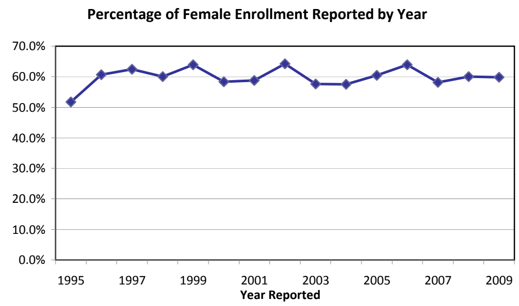


Table 21. NIH Fifteen Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2009: Enrollment by Race and Ethnicity

21A. FIFTEEN YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER AND MINORITY CATEGORIES IN ALL PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Form	Females		Males		Unknown		Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories		Number of Protocols with Enrollment data (Old + New Forms):
1995	1994	Old	528,421		459,921		33,151		1,021,493	374,433		3,188
	%		51.7%		45.0%		3.2%		100.0%	36.7%		
1996	1995	Old	4,130,385		2,583,865		91,054		6,805,304	2,125,958		6,036
	%		60.7%		38.0%		1.3%		100.0%	31.2%		
1997	1996	Old	3,320,610		1,930,783		65,540		5,316,933	1,709,223		5,692
	%		62.5%		36.3%		1.2%		100.0%	32.2%		
1998	1997	Old	4,246,130		2,716,880		115,566		7,078,576	2,923,662		7,602
	%		60.0%		38.4%		1.6%		100.0%	41.3%		
1999	1998	Old	5,102,306		2,712,068		169,863		7,984,237	3,108,228		8,285
	%		63.9%		34.0%		2.1%		100.0%	38.9%		
2000	1999	Old	5,585,042		3,919,065		64,990		9,569,097	3,406,297		9,390
	%		58.4%		41.0%		0.7%		100.0%	35.6%		
2001	2000	Old	6,808,822		4,740,887		44,547		11,594,256	3,619,119		10,212
	%		58.7%		40.9%		0.4%		100.0%	31.1%		
2002	2001	Old + New	7,155,549		3,904,560		78,375		11,138,484	3,666,880		8,945
	%		64.2%		35.1%		0.7%		100%	32.9%		
2003	2002	Old + New	8,514,481		6,121,496		136,277		14,772,254	5,387,692		10,216
	%		57.6%		41.4%		0.9%		100.0%	36.5%		
2004	2003	Old + New	10,889,097		7,741,892		292,931		18,923,920	7,611,611		10,125
	%		57.5%		40.9%		1.5%		100.0%	40.2%		
2005	2004	Old + New	9,503,922		5,941,907		276,923		15,722,752	6,245,436		10,233
			60.4%		37.8%		1.8%		100.0%	39.7%		
2006	2005	Old + New	9,473,273		5,172,205		185,452		14,830,930	6,388,316		10,758
			63.9%		34.9%		1.25%		100.0%	43.1%		
2007	2006	Old + New	10,152,590		6,887,793		408,075		17,448,458	5,783,543		10,914
			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
			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
			59.8%		39.6%		0.67%		100.0%	30.2%		


Percentage of Female Enrollment Reported by Year

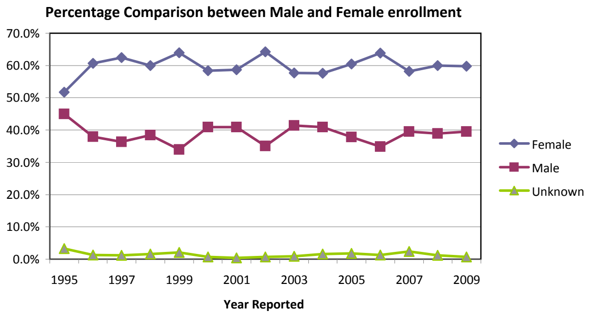

Percentage Comparison between Male and Female enrollment

Table 21A Comments:

1. Table 21A summarizes enrollment by sex/gender and minority race/ethnicity categories for the fifteen year reporting period (1995-2009). The data are compiled from Tables 21B, 21C and 21D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 21B) and the NEW Enrollment Form (Tables 21C and 21D).

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).

Table 21. NIH Thirteen Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2007: Enrollment by Race and Ethnicity

Notes Tables B-D

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

NOTE 2: Data from Tables 21B, 21C and 21D are combined to provide the summary data in Table 21A.

21B. OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/Other		Total	Subtotal Using US Minority Categories (shaded): OLD FORM		Number Protocols with Enrollment data (Old Form):
1995	**1994**	11,221	38,952	234,976	89,284	540,313	106,747		**1,021,493**	**374,433**		**3,188**
	%	1.1%	3.8%	23.0%	8.7%	52.9%	10.5%		100.0%	36.7%		
1996	**1995**	146,319	617,211	823,102	539,326	4,114,249	565,097		**6,805,304**	**2,125,958**		**6,036**
	%	2.2%	9.1%	12.1%	7.9%	60.5%	8.3%		100.0%	31.2%		
1997	**1996**	36,638	321,479	864,102	487,004	3,199,778	407,932		**5,316,933**	**1,709,223**		**5,692**
	%	0.7%	6.0%	16.3%	9.2%	60.2%	7.7%		100.0%	32.1%		
1998	**1997**	85,957	1,237,030	1,096,218	504,457	3,713,759	441,155		**7,078,576**	**2,923,662**		**7,602**
	%	1.2%	17.5%	15.5%	7.1%	52.5%	6.2%		100.0%	41.3%		
1999	**1998**	71,436	1,429,022	1,081,210	526,560	4,470,966	405,043		**7,984,237**	**3,108,228**		**8,285**
	%	0.9%	17.9%	13.5%	6.6%	56.0%	5.1%		100.0%	38.9%		
2000	**1999**	82,728	1,525,392	1,209,769	588,408	5,588,942	573,858		**9,569,097**	**3,406,297**		**9,390**
	%	0.9%	15.9%	12.6%	6.1%	58.4%	6.0%		100.0%	35.6%		
2001	**2000**	105,067	1,495,279	1,199,625	819,148	7,314,449	660,688		**11,594,256**	**3,619,119**		**10,212**
	%	0.9%	12.9%	10.3%	7.1%	63.1%	5.7%		100.0%	31.2%		
2002	**2001**	45,843	1,222,296	702,234	398,657	4,044,052	321,349		**6,734,431**	**2,369,030**		**6,187**
	%	0.7%	18.1%	10.4%	5.9%	60.1%	4.8%		100.0%	35.2%		
2003	**2002**	36,579	730,542	472,426	288,523	3,238,284	278,901		**5,045,255**	**1,528,070**		**4,903**
	%	0.7%	14.5%	9.4%	5.7%	64.2%	5.5%		100.0%	30.3%		
2004	**2003**	29,387	307,052	342,188	214,322	2,348,529	172,130		**3,413,608**	**892,949**		**2,782**
	%	0.9%	9.0%	10.0%	6.3%	68.8%	5.0%		100.0%	26.2%		
2005	**2004**	22,375	254,598	229,615	134,972	1,267,089	102,405		**2,011,054**	**641,560**		**1,786**
	%	1.1%	12.7%	11.4%	6.7%	63.0%	5.1%		100.0%	31.9%		
2006	**2005**	19,648	131,786	148,948	78,596	883,041	63,231		**1,325,250**	**378,978**		**1,391**
	%	1.5%	9.9%	11.2%	5.9%	66.6%	4.8%		100.0%	28.6%		
2007	**2006**	5,372	51,742	238,004	83,192	1,097,387	48,630		**1,524,327**	**378,310**		**1,098**
	%	0.4%	3.4%	15.6%	5.5%	72.0%	3.2%		100.0%	24.8%		
2008	**2007**	1,930	16,258	99,164	28,819	460,533	19,715		**626,419**	**146,171**		**915**
	%	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**
	%	0.3%	3.0%	10.9%	5.0%	76.8%	4.1%		100.0%	19.1%		

ORIENTATION TO TABLES 21C and 21D.

1. The New Form consists of Parts A and B (Tables 21C and 21D) for reporting years 2002-2009. This Form is provided as part of the annual progress report.

2. Table 21C displays the New Form Part A for reporting separate race and ethnicity data.

3. Table 21D 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.

21C. New Form Part A: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and

Total of All Subjects by Race										Total of All Subjects by Ethnicity			
FY Reported	**FY Funded**	**American Indian/ Alaska Native**	**Asian**	**Black or African American**	**Hawaiian /Pacific Islander**	**White**	**More Than One Race**	**Unknown /Other**	**Total***	**Not Hispanic**	**Hispanic or Latino****	**Unknown /Not Reported**	**Total***
2002	**2001**	77,734	354,049	547,776	21,636	2,651,541	30,955	720,362	**4,404,053**	3,071,952	292,429	1,039,672	**4,404,053**
	%	1.8%	8.0%	12.4%	0.5%	60.2%	0.7%	16.4%	100.0%	69.8%	6.6%	23.6%	100.0%
2003	**2002**	63,544	2,138,002	960,090	37,569	5,415,710	99,462	1,012,622	**9,726,999**	8,162,259	611,641	953,099	**9,726,999**
	%	0.7%	22.0%	9.9%	0.4%	55.7%	1.0%	10.4%	100.0%	83.9%	6.3%	9.8%	100.0%
2004	**2003**	98,047	4,345,396	1,379,857	54,452	8,065,069	186,241	1,381,250	**15,510,312**	13,168,842	756,339	1,585,131	**15,510,312**
	%	0.6%	28.0%	8.9%	0.4%	52.0%	1.2%	8.9%	100.0%	84.9%	4.9%	10.2%	100.0%
2005	**2004**	292,215	3,046,370	1,358,262	53,286	7,672,890	182,953	1,105,722	**13,711,698**	11,804,164	773,939	1,133,595	**13,711,698**
	%	2.1%	22.2%	9.9%	0.4%	56.0%	1.3%	8.1%	100.0%	86.1%	5.6%	8.3%	100.0%
2006	**2005**	141,567	3,463,202	1,251,339	38,460	7,089,017	321,554	1,200,541	**13,505,680**	11,308,244	1,054,313	1,143,123	**13,505,680**
	%	1.0%	25.6%	9.3%	0.3%	52.5%	2.4%	8.9%	100.0%	83.7%	7.8%	8.5%	100.0%
2007	**2006**	145,417	1,356,900	2,012,695	57,149	10,341,483	278,068	1,732,419	**15,924,131**	13,017,124	1,169,092	1,737,915	**15,924,131**
	%	0.9%	8.5%	12.6%	0.4%	64.9%	1.7%	10.9%	100.0%	81.7%	7.3%	10.9%	100.0%
2008	**2007**	134,494	1,168,053	1,835,035	48,560	9,651,267	181,941	1,766,586	**14,785,936**	11,881,644	1,116,699	1,787,594	**14,785,937**
	%	0.9%	7.9%	12.4%	0.3%	65.3%	1.2%	11.9%	100.0%	80.4%	7.6%	12.1%	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**	16,033,547	1,302,944	1,412,781	**18,749,272**
	%	0.8%	9.8%	12.2%	0.3%	68.2%	1.7%	6.9%	100.0%	85.5%	6.9%	7.5%	100.0%

21D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown/Other	Total Hispanic or Latino**	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Protocols with Enrollment data (New Form):
2002	**2001**	4,867	1,305	13,066	101	159,252	7390	106,448	**292,429**	**1,297,850**		**2,758**
	%	1.7%	0.4%	4.5%	0.0%	54.5%	2.5%	36.4%	100.0%	29.5%		
2003	**2002**	5,400	1,953	14,566	679	350,439	28,088	210,516	**611,641**	**3,859,622**		**5,313**
	%	0.9%	0.3%	2.4%	0.1%	57.3%	4.6%	34.4%	100.0%	39.7%		
2004	**2003**	6,408	5,040	25,276	2,037	361,112	62,909	293,557	**756,339**	**6,718,662**		**7,343**
	%	0.8%	0.7%	3.3%	0.3%	47.7%	8.3%	38.8%	100.0%	43.3%		
2005	**2004**	22,739	7,816	19,446	1,981	388,874	51,166	281,916	**773,938**	**5,603,876**		**8,447**
	%	2.9%	1.0%	2.5%	0.3%	50.2%	6.6%	36.4%	100.0%	40.9%		
2006	**2005**	45,074	6,641	21,712	2,193	417,495	185,477	375,721	**1,054,313**	**6,009,338**		**9,367**
	%	4.3%	0.6%	2.1%	0.2%	39.6%	17.6%	35.6%	100.0%	44.5%		
2007	**2006**	37,581	7,414	31,239	4,310	538,216	100,197	450,135	**1,169,092**	**4,356,434**		**9,816**
	%	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**	**4,265,935**		**10,130**
	%	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**	**5,708,972**		**10,328**
	%	3.0%	4.1%	7.0%	0.2%	56.0%	4.9%	24.8%	100.0%	30.4%		

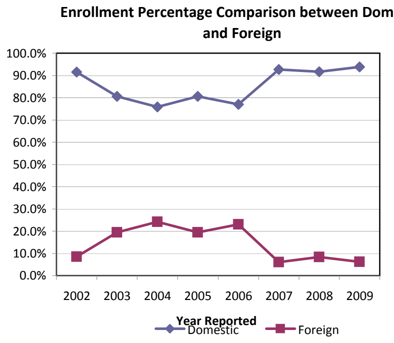
*** These totals must agree.**

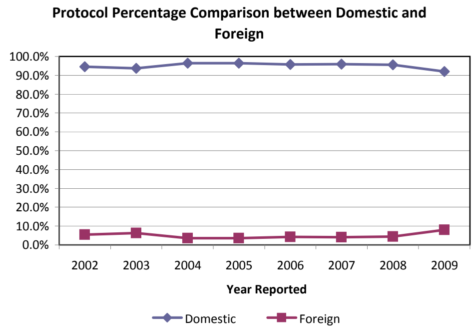
****These totals must agree.**

Table 21. NIH Eight Year Minority Trend Summary of NIH Extramural and Intramural Clinical

21E. Comparison of Domestic and Foreign Enrollment & Protocols with Total Enrollment for the period FY2002-2009

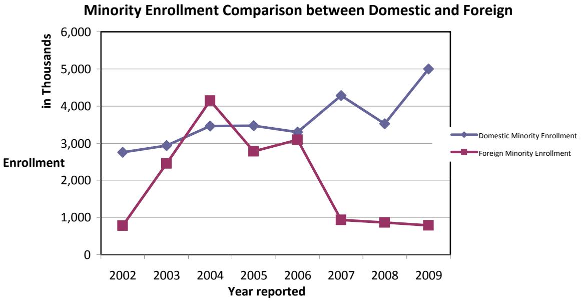
		ENROLLMENT					PROTOCOLS				
FY Reported	**FY Funded**	**Total Enrollment data (Old + New Forms):**	**Total DOMESTIC Enrollment**	**Percent DOMESTIC Enrollment**	**Total FOREIGN Enrollment**	**Percent FOREIGN Enrollment**	**Number of Protocols with Enrollment data (Old + New Forms):**	**Number of DOMESTIC Protocols**	**Percent Domestic Protocols**	**Number of FOREIGN Protocols**	**Percent Foreign Protocols**
2002	**2001**	**11,138,484**	**10,192,401**	**91.5%**	**946,083**	**8.5%**	**8,945**	**8,463**	**94.6%**	**482**	**5.4%**
2003	**2002**	**14,772,254**	**11,911,357**	**80.6%**	**2,860,897**	**19.4%**	**10,216**	**9,578**	**93.8%**	**638**	**6.2%**
2004	**2003**	**18,923,920**	**14,359,793**	**75.9%**	**4,564,127**	**24.1%**	**10,125**	**9,760**	**96.4%**	**365**	**3.6%**
2005	**2004**	**15,722,752**	**12,669,858**	**80.6%**	**3,052,894**	**19.4%**	**10,233**	**9,862**	**96.4%**	**371**	**3.6%**
2006	**2005**	**14,830,930**	**11,425,701**	**77.0%**	**3,405,229**	**23.0%**	**10,758**	**10,294**	**95.7%**	**464**	**4.3%**
2007	**2006**	**17,448,458**	**16,180,588**	**92.7%**	**1,267,870**	**6.1%**	**10,914**	**10,463**	**95.9%**	**451**	**4.1%**
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**	**17,962,879**	**93.9%**	**1,175,859**	**6.1%**	**11,171**	**10,269**	**91.9%**	**902**	**8.1%**

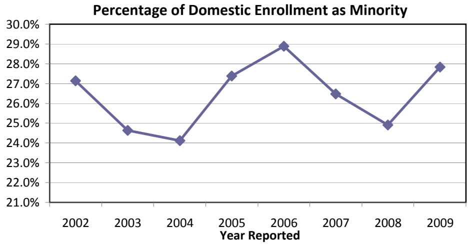

Enrollment Percentage Comparison between Domestic and Foreign


Protocol Percentage Comparison between Domestic and Foreign

21F. Comparison of Domestic and Foreign Minority Participation for FY 2002-2009

FY Reported	FY Funded	FOREIGN Minority	Foreign Total	DOMESTIC Minority	Domestic Total
2002	2001	777,461	946,083	2,754,820	10,149,869
		82.2%	100.0%	27.1%	100.0%
2003	2002	2,452,329	2,860,897	2,935,363	11,911,357
		85.7%	100.0%	24.6%	100.0%
2004	2003	4,147,255	4,564,127	3,464,356	14,359,793
		90.9%	100.0%	24.1%	100.0%
2005	2004	2,776,565	3,052,894	3,468,864	12,669,858
		90.9%	100.0%	27.4%	100.0%
2006	2005	3,087,181	3,405,229	3,301,135	11,425,701
		90.7%	100.0%	28.9%	100.0%
2007	2006	932,686	1,267,870	4,283,738	16,180,588
		73.6%	100.0%	26.5%	100.0%
2008	2007	864,945	1,277,728	3,521,691	14,134,627
		67.7%	100.0%	24.9%	100.0%
2009	2008	784,944	1,175,859	4,998,599	17,962,879
		66.8%	100.0%	27.8%	100.0%





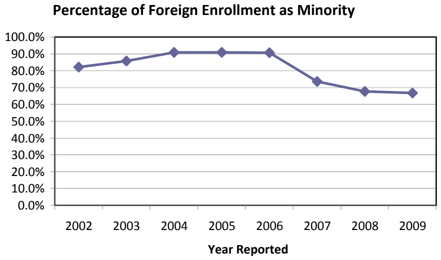


Table 22: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported: FY2002-2009: Enrollment Using U.S. Race/Ethnicity Categories

22A . EIGHT YEAR SUMMARY TOTALS: SUBJECTS IN DOMESTIC PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**6,583,087**	**3,506,787**	**59,995**	**10,149,869**	**2,754,820**	**8,425**
	%	64.9%	34.6%	0.6%	100.0%	27.1%	
2003	**2002**	**7,392,404**	**4,393,496**	**125,457**	**11,911,357**	**2,935,363**	**9,578**
	%	62.1%	36.9%	1.1%	100.0%	24.6%	
2004	**2003**	**8,881,299**	**5,199,765**	**278,729**	**14,359,793**	**3,464,356**	**9,760**
	%	61.8%	36.2%	1.9%	100.0%	24.1%	
2005	**2004**	**7,887,209**	**4,515,242**	**267,407**	**12,669,858**	**3,468,864**	**9,862**
		62.3%	35.6%	2.1%	100.0%	27.4%	
2006	**2005**	**7,684,453**	**3,566,577**	**174,671**	**11,425,701**	**3,301,135**	**10,294**
		67.3%	31.2%	1.5%	100.0%	28.9%	
2007	**2006**	**9,397,957**	**6,389,817**	**392,814**	**16,180,588**	**4,283,738**	**10,463**
		58.1%	39.5%	2.4%	100.0%	26.5%	
2008	**2007**	**8,514,768**	**5,451,624**	**168,235**	**14,134,627**	**3,409,896**	**10,548**
		60.2%	38.6%	1.2%	100.0%	24.1%	
2009	**2008**	**10,748,744**	**7,093,702**	**120,433**	**17,962,879**	**4,998,599**	**10,269**
		59.8%	39.5%	0.7%	100.0%	27.8%	

NOTE on FY2002 Reported Data:

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

NOTE on FY2003 Reported Data:

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

NOTE on FY2004 Reported Data:

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

NOTE on FY2005 Reported Data:

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

NOTE on FY2006 Reported Data:

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

NOTE of FY2007 Reported Data:

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

Table 22: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2009: Enrollment Using U.S. Race/Ethnicity Categories

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

NOTE 2: Data from Tables 22B, 22C and 22D are combined to provide the summary data in Table A.

22B. OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other		Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority Categories (shaded): OLD FORM		Number of Domestic Protocols with Enrollment data (Old Form):
2002	**2001**	45,639	752,203	673,726	378,300	3,880,431	316,053		6,046,352	1,849,868		**5,783**
	%	0.8%	12.4%	11.1%	6.3%	64.2%	5.2%		100.0%	30.6%		
2003	**2002**	36,238	249,420	455,329	264,336	3,100,815	266,339		4,372,477	1,005,323		**4,478**
	%	0.8%	5.7%	10.4%	6.0%	70.9%	6.1%		100.0%	23.0%		
2004	**2003**	28,953	196,647	322,078	194,762	2,273,619	157,464		3,173,523	742,440		**2,702**
	%	0.9%	6.2%	10.1%	6.1%	71.6%	5.0%		100.0%	23.4%		
2005	**2004**	22,375	89,119	210,465	126,351	1,245,337	93,239		1,786,886	448,310		**1,736**
	%	1.3%	5.0%	11.8%	7.1%	69.7%	5.2%		100.0%	25.1%		
2006	**2005**	19,628	51,701	148,224	74,312	866,683	61,480		1,222,028	293,865		**1,361**
	%	1.6%	4.2%	12.1%	6.1%	70.9%	5.0%		100.0%	24.0%		
2007	**2006**	5,372	51,740	238,003	81,677	1,095,702	48,625		1,521,119	376,792		**1,092**
	%	0.4%	3.4%	15.6%	5.4%	72.0%	3.2%		100.0%	24.8%		
2008	**2007**	12,505	11,366	62,753	25,171	350,300	160,259		622,354	111,795		**909**
	%	2.0%	1.8%	10.1%	4.0%	56.3%	25.8%		100.0%	18.0%		
2009	**2008**	1,165	11,204	42,213	18,019	284,717	14,700		372,018	72,601		**729**
	%	0.3%	3.0%	11.3%	4.8%	76.5%	4.0%		100.0%	19.5%		

22C. NEW FORM PART A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

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

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/Not Reported	*Total of All Subjects by Ethnic Category
2002	**2001**	74,593	174,215	473,699	7,623	2,626,547	30,200	716,640	4,103,517	2,785,590	285,921	1,032,006	4,103,517
	%	1.8%	4.2%	11.5%	0.2%	64.0%	0.7%	17.5%	100.0%	67.9%	7.0%	25.1%	100.0%
2003	**2002**	61,526	295,061	897,518	23,068	5,161,965	94,138	1,005,604	7,538,880	6,003,326	602,018	933,536	7,538,880
	%	0.8%	3.9%	11.9%	0.3%	68.5%	1.2%	13.3%	100.0%	79.6%	8.0%	12.4%	100.0%
2004	**2003**	97,854	485,137	1,280,129	42,945	7,772,927	172,185	1,335,093	11,186,270	8,893,158	720,551	1,572,561	11,186,270
	%	0.9%	4.3%	11.4%	0.4%	69.5%	1.5%	11.9%	100.0%	79.5%	6.4%	14.1%	100.0%
2005	**2004**	291,044	655,959	1,232,957	42,993	7,485,193	164,096	1,010,730	10,882,972	9,120,293	721,138	1,041,541	10,882,972
	%	2.7%	6.0%	11.3%	0.4%	68.8%	1.5%	9.3%	100.0%	83.8%	6.6%	9.6%	100.0%
2006	**2005**	111,048	946,613	1,032,199	35,142	6,844,960	178,275	1,055,436	10,203,673	8,384,360	796,556	1,022,757	10,203,673
	%	1.1%	9.3%	10.1%	0.3%	67.1%	1.7%	10.3%	100.0%	82.2%	7.8%	10.0%	100.0%
2007	**2006**	129,830	892,410	1,719,631	46,569	10,028,992	270,005	1,572,032	14,659,469	11,991,388	1,002,302	1,665,779	14,659,469
	%	0.9%	6.1%	11.7%	0.3%	68.4%	1.8%	10.7%	100.0%	81.8%	6.8%	11.4%	100.0%
2008	**2007**	111,668	719,287	1,582,616	41,780	9,256,041	168,750	1,632,131	13,512,273	10,871,618	945,603	1,695,053	13,512,274
	%	0.8%	5.3%	11.7%	0.3%	68.5%	1.2%	12.1%	100.0%	80.5%	7.0%	12.5%	100.0%
2009	**2008**	145,541	1,396,409	2,066,817	47,981	12,387,427	302,563	1,244,123	17,590,861	15,090,139	1,142,171	1,358,551	17,590,861
	%	0.8%	7.9%	11.7%	0.3%	70.4%	1.7%	7.1%	100.0%	85.8%	6.5%	7.7%	100.0%

22D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	Domestic Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Domestic Protocols with Enrollment data (New Form):
2002	**2001**	1,163	436	12,005	98	69,313	5,626	75,309	163,950	**904,952**		**2,642**
	%	0.7%	0.3%	7.3%	0.1%	42.3%	3.4%	45.9%	100.0%	22.1%		
2003	**2002**	3,756	1,950	13,345	678	349,844	23,560	208,885	602,018	**1,930,040**		**5,100**
	%	0.6%	0.3%	2.2%	0.1%	58.1%	3.9%	34.7%	100.0%	25.6%		
2004	**2003**	6,293	5,026	12,498	2,037	356,575	51,031	287,091	720,551	**2,721,916**		**7,058**
	%	0.9%	0.7%	1.7%	0.3%	49.5%	7.1%	39.8%	100.0%	24.3%		
2005	**2004**	22,057	7,810	19,282	1,981	362,707	36,503	270,798	721,138	**3,020,554**		**8,126**
	%	3.1%	1.1%	2.7%	0.3%	50.3%	5.1%	37.6%	100.0%	27.8%		
2006	**2005**	15,498	6,540	19,870	1,505	374,830	49,150	329,163	796,556	**3,007,270**		**8,933**
	%	1.9%	0.8%	2.5%	0.2%	47.1%	6.2%	41.3%	100.0%	29.5%		
2007	**2006**	20,932	6,875	28,078	3,199	493,196	94,717	355,305	1,002,302	**3,906,946**		**9,371**
	%	2.1%	0.7%	2.8%	0.3%	49.2%	9.4%	35.4%	100.0%	26.7%		
2008	**2007**	14,528	7,086	84,215	2,361	468,176	51,618	317,619	945,603	**3,409,896**		**9,578**
	%	1.5%	0.7%	8.9%	0.2%	49.5%	5.5%	33.6%	100.0%	25.2%		
2009	**2008**	31,044	8,899	82,054	3,098	680,898	50,573	285,789	1,142,355	**4,925,998**		**9,540**
	%	2.7%	0.8%	7.2%	0.3%	59.6%	4.4%	25.0%	100.0%	28.0%		

*** These totals must agree**

**** These totals must agree**

Table 23: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2009:Enrollment Using U.S. Race/Ethnicity Categories

23A . Phase III EIGHT YEAR SUMMARY TOTALS: SUBJECTS IN DOMESTIC PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	2001	264,517	179,179	740	444,436	92,961	582
	%	59.5%	40.3%	0.2%	100.0%	20.9%	
2003	2002	266,913	218,166	1,778	486,857	109,376	643
	%	54.8%	44.8%	0.4%	100.0%	22.5%	
2004	2003	277,333	217,890	1,018	496,241	125,813	549
	%	55.9%	43.9%	0.2%	100.0%	25.4%	
2005	2004	261,589	174,137	2,176	437,902	109,910	517
		59.7%	39.8%	0.5%	100.0%	25.1%	
2006	2005	258,467	137,621	4,209	400,297	83,034	564
		64.6%	34.4%	1.1%	100.0%	20.7%	
2007	2006	228,289	183,878	16,273	428,440	88,339	609
		53.3%	42.9%	3.8%	100.0%	20.6%	
2008	2007	347,982	226,266	16,857	591,105	119,382	585
		58.9%	38.3%	2.9%	100.0%	20.2%	
2009	2008	287,455	231,173	30,072	548,700	211,884	457
		52.4%	42.1%	5.5%	100.0%	38.6%	

Table 23: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2009: Enrollment Using U.S. Race/Ethnicity Categories

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

NOTE 2: Data from Tables 23B, 23C and 23D are combined to provide the summary data in Table A.

23B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other	Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Domestic Protocols with Enrollment data (Old Form):
2002	2001	1,586	8,291	49,184	27,912	305,964	10,670	403,607	86,973	494
	%	0.4%	2.1%	12.2%	6.9%	75.8%	2.6%	100.0%	21.5%	
2003	2002	1,612	7,610	48,975	25,567	322,600	8,538	414,902	83,764	468
	%	0.4%	1.8%	11.8%	6.2%	77.8%	2.1%	100.0%	20.2%	
2004	2003	1,504	6,739	45,233	31,967	262,671	6,447	354,561	85,443	286
	%	0.4%	1.9%	12.8%	9.0%	74.1%	1.8%	100.0%	24.1%	
2005	2004	1,319	5,488	39,401	20,646	229,235	4,493	300,582	66,854	205
	%	0.4%	1.8%	13.1%	6.9%	76.3%	1.5%	100.0%	22.2%	
2006	2005	996	4,505	20,325	9,512	171,191	5,673	212,202	35,338	207
	%	0.5%	2.1%	9.6%	4.5%	80.7%	2.7%	100.0%	16.7%	
2007	2006	751	3,941	21,581	9,331	168,127	4,254	207,985	35,604	204
	%	0.4%	1.9%	10.4%	4.5%	80.8%	2.0%	100.0%	17.1%	
2008	2007	885	4,506	22,431	9,636	187,719	4,171	229,348	37,458	162
	%	0.4%	2.0%	9.8%	4.2%	81.8%	1.8%	100.0%	16.3%	
2009	2008	569	2,861	14,768	6,270	122,713	3,258	150,439	24,468	124
	%	0.4%	1.9%	9.8%	4.2%	81.6%	2.2%	100.0%	16.3%	

23C. NEW FORM Part A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the

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

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	**2001**	159	798	3,199	52	34,541	560	1,520	40,829	34,662	1,629	4,538	40,829
	%	0.4%	2.0%	7.8%	0.1%	84.6%	1.4%	3.7%	100.0%	84.9%	4.0%	11.1%	100.0%
2003	**2002**	477	2,586	14,031	220	46,774	989	6,878	71,955	55,575	7,828	8,552	71,955
	%	0.7%	3.6%	19.5%	0.3%	65.0%	1.4%	9.6%	100.0%	77.2%	10.9%	11.9%	100.0%
2004	**2003**	1,396	4,373	22,307	611	106,260	1,849	4,884	141,680	123,770	10,863	7,047	141,680
	%	1.0%	3.1%	15.7%	0.4%	75.0%	1.3%	3.4%	100.0%	87.4%	7.7%	5.0%	100.0%
2005	**2004**	1,775	4,920	24,390	462	93,662	3,063	9,048	137,320	118,528	9,773	9,019	137,320
	%	1.3%	3.6%	17.8%	0.3%	68.2%	2.2%	6.6%	100.0%	86.3%	7.1%	6.6%	100.0%
2006	**2005**	2,724	5,312	23,267	530	118,577	4,077	33,608	188,095	141,688	13,550	32,857	188,095
	%	1.4%	2.8%	12.4%	0.3%	63.0%	2.2%	17.9%	100.0%	75.3%	7.2%	17.5%	100.0%
2007	**2006**	2,314	4,294	21,141	553	130,085	3,974	58,094	220,455	146,482	21,600	52,373	220,455
	%	1.0%	1.9%	9.6%	0.3%	59.0%	1.8%	26.4%	100.0%	66.4%	9.8%	23.8%	100.0%
2008	**2007**	2,256	6,314	25,753	713	276,406	11,836	38,279	361,557	289,525	42,003	30,229	361,757
	%	0.6%	1.7%	7.1%	0.2%	76.4%	3.3%	10.6%	100.0%	80.0%	11.6%	8.4%	100.0%
2009	**2008**	17,475	83,173	54,778	844	183,320	4,672	53,999	398,261	315,006	44,227	39,028	398,261
	%	4.4%	20.9%	13.8%	0.2%	46.0%	1.2%	13.6%	100.0%	79.1%	11.1%	9.8%	100.0%

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

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	Domestic Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Domestic Protocols with Enrollment data (New Form):
2002	**2001**	49	21	31	4	660	304	560	1,629	**5,988**		**88**
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	14.7%		
2003	**2002**	37	70	186	23	2,113	203	5,196	7,828	**25,612**		**175**
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	35.6%		
2004	**2003**	269	59	193	26	7,262	482	2,572	10,863	**40,370**		**263**
	%	2.5%	0.5%	1.8%	0.2%	66.9%	4.4%	23.7%	100.0%	28.5%		
2005	**2004**	371	42	446	45	3,663	423	4,783	9,773	**43,056**		**312**
	%	3.8%	0.4%	4.6%	0.5%	37.5%	4.3%	48.9%	100.0%	31.4%		
2006	**2005**	458	47	507	40	5,544	712	6,242	13,550	**47,696**		**357**
	%	3.4%	0.3%	3.7%	0.3%	40.9%	5.3%	46.1%	100.0%	25.4%		
2007	**2006**	300	44	454	24	7,360	319	13,099	21,600	**52,735**		**405**
	%	1.4%	0.2%	2.1%	0.1%	34.1%	1.5%	60.6%	100.0%	23.9%		
2008	**2007**	518	228	714	122	22,244	5,369	12,808	42,003	**81,924**		**423**
	%	1.2%	0.5%	1.7%	0.3%	53.0%	12.8%	30.5%	100.0%	22.7%		
2009	**2008**	15,312	350	930	197	11,096	964	15,378	44,227	**187,416**		**333**
	%	34.6%	0.8%	2.1%	0.4%	25.1%	2.2%	34.8%	100.0%	47.1%		

*** These totals must agree**

**** These totals must agree**

Table 24. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2009: Enrollment Using U.S. Race/Ethnicity Categories

24A . Eight Year Summary Totals: Subjects in Foreign Protocols (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**553,056**	**379,294**	**13,833**	**946,083**	**777,461**	**482**
	%	58.5%	40.1%	1.5%	100.0%	82.2%	
2003	**2002**	**1,122,077**	**1,728,000**	**10,820**	**2,860,897**	**2,452,329**	**638**
	%	39.2%	60.4%	0.4%	100.0%	85.7%	
2004	**2003**	**2,007,798**	**2,542,127**	**14,202**	**4,564,127**	**4,147,255**	**365**
	%	44.0%	55.7%	0.3%	100.0%	90.9%	
2005	**2004**	**1,616,713**	**1,426,665**	**9,516**	**3,052,894**	**2,776,565**	**371**
	%	53.0%	46.7%	0.3%	100.0%	90.9%	
2006	**2005**	**1,788,820**	**1,605,628**	**10,781**	**3,405,229**	**3,087,181**	**464**
	%	52.5%	47.2%	0.3%	100.0%	90.7%	
2007	**2006**	**754,633**	**497,976**	**15,261**	**1,267,870**	**932,686**	**451**
	%	59.5%	39.3%	1.2%	100.0%	73.6%	
2008	**2007**	**729,198**	**540,115**	**8,415**	**1,277,728**		**497**
	%	57.1%	42.3%	0.7%	100.0%	0.0%	
2009	**2008**	**690,399**	**476,944**	**8,516**	**1,175,859**		**902**
	%	58.7%	40.6%	0.7%	100.0%	0.0%	

NOTE on FY2002 Reported Data:

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

NOTE on FY2003 Reported Data:

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

NOTE on FY2004 Reported Data:

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

NOTE on FY2005 Reported Data:

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

NOTE on FY2006 Reported Data:

NOTE on FY2007 Reported Data:

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

Table 24. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2009: Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority
NOTE 2: Data from Tables 24B, 24C and 24D are combined to provide the summary data in Table A.

24B.OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other		Total Foreign Enrollment (Old Form)	FOREIGN Subtotal Using US Minority Categories (shaded): OLD FORM		Number of Foreign Protocols with Enrollment data (Old Form):
2002	2001	69	468,958	21,407	19,075	143,768	3,565		656,842	509,509		380
	%	0.0%	71.4%	3.3%	2.9%	21.9%	0.5%		100.0%	77.6%		
2003	2002	341	481,122	17,097	24,187	137,469	12,562		672,778	522,747		425
	%	0.1%	71.5%	2.5%	3.6%	20.4%	1.9%		100.0%	77.7%		
2004	2003	434	110,405	20,110	19,560	74,910	14,666		240,085	150,509		80
	%	0.2%	46.0%	8.4%	8.1%	31.2%	6.1%		100.0%	62.7%		
2005	2004	0	165,479	19,150	8,621	21,752	9,166		224,168	193,250		50
	%	0.0%	73.8%	8.5%	3.8%	9.7%	4.1%		100.0%	86.2%		
2006	2005	20	80,085	724	4,284	16,358	1,751		103,222	85,113		30
	%	0.0%	77.6%	0.7%	4.2%	15.8%	1.7%		100.0%	82.5%		
2007	2006	0	2	1	1,515	1,685	5		3,208	1,518		6
	%	0.0%	0.1%	0.0%	47.2%	52.5%	0.2%		100.0%	47.3%		
2008	2007	15	26	14	852	3,057	91		4,055	917		6
	%	0.4%	0.6%	0.3%	21.0%	75.4%	2.2%		100.0%	22.6%		
2009	2008	48	448	192	1,282	14,398	1,080		17,448	1,970		114
	%	0.3%	2.6%	1.1%	7.3%	82.5%	6.2%		100.0%	11.3%		

24C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

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

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	3,271	180,022	68,071	14,013	19,970	741	3,153	289,241	278,618	6,064	4,559	289,241
	%	1.1%	62.2%	23.5%	4.8%	6.9%	0.3%	1.1%	100.0%	96.3%	2.1%	1.6%	100.0%
2003	2002	2,018	1,842,941	62,572	14,501	253,745	5,324	7,018	2,188,119	2,158,933	9,623	19,563	2,188,119
	%	0.1%	84.2%	2.9%	0.7%	11.6%	0.2%	0.3%	100.0%	98.7%	0.4%	0.9%	100.0%
2004	2003	193	3,860,259	99,728	11,507	292,142	14,056	46,157	4,324,042	4,275,684	35,788	12,570	4,324,042
	%	0.0%	89.3%	2.3%	0.3%	6.8%	0.3%	1.1%	100.0%	98.9%	0.8%	0.3%	100.0%
2005	2004	1,171	2,390,404	125,305	10,293	187,697	18,857	94,999	2,828,726	2,683,871	52,801	92,054	2,828,726
	%	0.0%	84.5%	4.4%	0.4%	6.6%	0.7%	3.4%	100.0%	94.9%	1.9%	3.3%	100.0%
2006	2005	30,519	2,516,589	219,140	3,318	244,057	143,279	145,105	3,302,007	2,923,885	257,756	120,366	3,302,007
	%	0.9%	76.2%	6.6%	0.1%	7.4%	4.3%	4.4%	100.0%	88.5%	7.8%	3.6%	100.0%
2007	2006	15,587	464,490	293,064	10,580	312,491	8,063	160,387	1,264,662	1,025,736	166,790	72,136	1,264,662
	%	1.2%	36.7%	23.2%	0.8%	24.7%	0.6%	12.7%	100.0%	81.1%	13.2%	5.7%	100.0%
2008	2007	21,218	449,034	258,425	6,795	403,766	13,405	121,020	1,273,663	1,021,912	171,728	80,023	1,273,663
	%	1.7%	35.3%	20.3%	0.5%	31.7%	1.1%	9.5%	100.0%	80.2%	13.5%	6.3%	100.0%
2009	2008	8,974	444,130	220,760	2,358	403,518	21,276	57,395	1,158,411	943,408	160,773	54,230	1,158,411
	%	0.8%	38.3%	19.1%	0.2%	34.8%	1.8%	5.0%	100.0%	81.4%	13.9%	4.7%	100.0%

24D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Foreign Protocols with Enrollment data (New Form):
2002	2001	1,461	0	4	0	1,659	683	175	3,982	**267,952**		102
	%	36.7%	0.0%	0.1%	0.0%	41.7%	17.2%	4.4%	100.0%	92.6%		
2003	2002	1,644	3	1,222	0	632	4,528	1,594	9,623	**1,929,582**		213
	%	17.1%	0.0%	12.7%	0.0%	6.6%	47.1%	16.6%	100.0%	88.2%		
2004	2003	115	14	12,778	0	4,537	11,878	6,466	35,788	**3,996,746**		285
	%	0.3%	0.0%	35.7%	0.0%	12.7%	33.2%	18.1%	100.0%	92.4%		
2005	2004	682	6	164	0	26,161	14,664	11,124	52,801	**2,583,315**		321
	%	1.3%	0.0%	0.3%	0.0%	49.5%	27.8%	21.1%	100.0%	91.3%		
2006	2005	29,576	101	1,842	688	42,665	136,326	46,558	257,756	**3,002,068**		434
	%	11.5%	0.0%	0.7%	0.3%	16.6%	52.9%	18.1%	100.0%	90.9%		
2007	2006	16,681	550	3,234	1,115	46,034	5,816	93,360	166,790	**931,178**		445
	%	10.0%	0.3%	1.9%	0.7%	27.6%	3.5%	56.0%	100.0%	73.6%		
2008	2007	19,786	24,515	1,042	1	49,995	11,253	65,156	171,748	**864,028**		492
	%	11.5%	14.3%	0.6%	0.0%	29.1%	6.6%	37.9%	100.0%	67.8%		
2009	2008	8,154	44,647	9,130	5	48,457	13,361	37,019	160,773	**782,974**		788
	%	5.1%	27.8%	5.7%	0.0%	30.1%	8.3%	23.0%	100.0%	67.6%		

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Table 25. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2009: Enrollment Using U.S. Race/Ethnicity Categories

25A. Part A. Phase III EIGHT YEAR SUMMARY TOTALS: SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)

FY Reported	FY Funded		Females		Males		Unknown		Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories		Number of Foreign Protocols with Enrollment data (Old + New Forms):
2002	**2001**		**14,359**		**15,911**		**41**		**30,311**	**18,308**		**172**
	%		47.4%		52.5%		0.1%		100.0%	60.4%		
2003	**2002**		**28,037**		**21,237**		**136**		**49,410**	**23,927**		**209**
	%		56.7%		43.0%		0.3%		100.0%	48.4%		
2004	**2003**		**24,020**		**25,023**		**83**		**49,126**	**37,126**		**24**
	%		48.9%		50.9%		0.2%		100.0%	75.6%		
2005	**2004**		**29,388**		**23,163**		**2,547**		**55,098**	**44,281**		**30**
	%		53.3%		42.0%		4.6%		100.0%	80.4%		
2006	**2005**		**55,599**		**42,354**		**1,180**		**99,133**	**84,412**		**60**
	%		56.1%		42.7%		1.2%		100.0%	85.2%		
2007	**2006**		**96,405**		**65,755**		**559**		**162,719**	**156,593**		**44**
	%		59.2%		40.4%		0.3%		100.0%	96.2%		
2008	**2007**		**107,608**		**93,488**		**377**		**201,473**	**188,851**		**52**
	%		53.4%		46.4%		0.2%		100.0%	93.7%		
2009	**2008**		**58,293**		**44,986**		**321**		**103,600**	**80,065**		**60**
	%		56.3%		43.4%		0.3%		100.0%	77.3%		

Table 25. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2009: Enrollment Using U.S. Race/Ethnicity Categories

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

NOTE 2: Data from Tables 25B, 25C and 25D are combined to provide the summary data in Table A.

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25B. OLD FORM: Inclusion enrollment report (Total of all foreign subjects reported using 1977 OMB standards)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/Other		Total Foreign Enrollment (Old Form)	FOREIGN Subtotal Using US Minority Categories (shaded): OLD FORM		Number of Foreign Protocols with Enrollment data (Old Form):
2002	**2001**	59	12,269	2,807	1,724	9,579	1,558		27,996	16,859		**166**
	%	0.2%	43.8%	10.0%	6.2%	34.2%	5.6%		100.0%	60.2%		
2003	**2002**	77	12,428	280	3,499	15,054	8,077		39,415	16,284		**188**
	%	0.2%	31.5%	0.7%	8.9%	38.2%	20.5%		100.0%	41.3%		
2004	**2003**	1	12,068	52	1,007	3,093	7,603		23,824	13,128		**10**
	%	0.0%	50.7%	0.2%	4.2%	13.0%	31.9%		100.0%	55.1%		
2005	**2004**	0	12,252	1	1,183	2,257	14		15,707	13,436		**5**
	%	0.0%	78.0%	0.0%	7.5%	14.4%	0.1%		100.0%	85.5%		
2006	**2005**	16	12,295	30	12	4,533	675		17,561	12,353		**8**
	%	0.1%	70.0%	0.2%	0.1%	25.8%	3.8%		100.0%	70.3%		
2007	**2006**	0	2	1	2	1,662	5		1,672	5		**1**
	%	0.0%	0.1%	0.1%	0.1%	99.4%	0.3%		100.0%	0.3%		
2008	**2007**	15	36	14	6	3,034	91		3,196	71		**2**
	%	0.5%	1.1%	0.4%	0.2%	94.9%	2.8%		100.0%	2.2%		
2009	**2008**	44	430	188	214	13,369	1,053		15,298	876		**72**
	%	0.3%	2.8%	1.2%	1.4%	87.4%	6.9%		100.0%	5.7%		

25C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

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

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/Not Reported	*Total of All Subjects by Ethnic Category
2002	**2001**	0	1	1,448	0	113	0	753	2,315	1,562	0	753	2,315
	%	0.0%	0.0%	62.5%	0.0%	4.9%	0.0%	32.5%	100.0%		0.0%	32.5%	32.5%
2003	**2002**	7	23	7,610	0	1,095	0	1,260	9,995	8,720	3	1,272	9,995
	%	0.1%	0.2%	76.1%	0.0%	11.0%	0.0%	12.6%	100.0%	87.2%	0.0%	12.7%	100.0%
2004	**2003**	0	12	21,414	0	553	2,570	753	25,302	21,972	2,572	758	25,302
	%	0.0%	0.0%	84.6%	0.0%	2.2%	10.2%	3.0%	100.0%	86.8%	10.2%	3.0%	100.0%
2005	**2004**	389	4,272	25,948	0	7,576	0	1,206	39,391	38,122	624	645	39,391
	%	1.0%	10.8%	65.9%	0.0%	19.2%	0.0%	3.1%	100.0%	96.8%	1.6%	1.6%	100.0%
2006	**2005**	1,906	27,048	27,513	5	8,093	169	26,838	91,572	60,670	17,484	3,418	81,572
	%	2.1%	29.5%	30.0%	0.0%	8.8%	0.2%	29.3%	100.0%	74.4%	21.4%	4.2%	100.0%
2007	**2006**	7,037	43,070	63,327	2	2,917	171	44,523	161,047	108,210	50,022	2,815	161,047
	%	4.4%	26.7%	39.3%	0.0%	1.8%	0.1%	27.6%	100.0%	67.2%	31.1%	1.7%	100.0%
2008	**2007**	12,550	88,982	77,421	3	4,949	301	14,071	198,277	171,357	22,354	4,566	198,277
	%	6.3%	44.9%	39.0%	0.0%	2.5%	0.2%	7.1%	100.0%	86.4%	11.3%	2.3%	100.0%
2009	**2008**	34	9,695	61,455	15	6,207	4	10,892	88,302	76,984	7,996	3,322	88,302
	%	0.0%	11.0%	69.6%	0.0%	7.0%	0.0%	12.3%	100.0%	87.2%	9.1%	3.8%	100.0%

25D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Foreign Protocols with Enrollment data (New Form):
2002	**2001**	0	0	0	0	0	0	0	0	**1,449**		**6**
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	62.6%		
2003	**2002**	0	0	0	0	2	0	1	3	**7,643**		**21**
	%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	33.3%	100.0%	76.5%		
2004	**2003**	0	0	0	0	2	2,570	0	2,572	**23,998**		**14**
	%	0.0%	0.0%	0.0%	0.0%	0.1%	99.9%	0.0%	100.0%	94.8%		
2005	**2004**	388	0	0	0	4	0	232	624	**30,845**		**25**
	%	62.2%	0.0%	0.0%	0.0%	0.6%	0.0%	37.2%	100.0%	78.3%		
2006	**2005**	1,849	3	213	0	1,328	1	14,090	17,484	**72,059**		**52**
	%	10.6%	0.0%	1.2%	0.0%	7.6%	0.0%	80.6%	100.0%	78.7%		
2007	**2006**	7,033	1	4	0	70	3	42,911	50,022	**156,588**		**43**
	%	14.1%	0.0%	0.0%	0.0%	0.1%	0.0%	85.8%	100.0%	97.2%		
2008	**2007**	12,538	0	1	0	130	292	9,393	22,354	**188,780**		**50**
	%	56.1%	0.0%	0.0%	0.0%	0.6%	1.3%	42.0%	100.0%	95.2%		
2009	**2008**	1	1	7	1	391	0	7,595	7,996	**79,189**		**101**
	%	0.0%	0.0%	0.1%	0.0%	4.9%	0.0%	95.0%	100.0%	89.7%		

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APPENDICES

Appendix A

Historical Narrative on the Implementation of the NIH Inclusion Policy

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

Historical Background

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

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

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

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

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

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

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

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

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

Continuing Implementation and Monitoring Activities: 2000 to the Present

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

- NIH issued guidelines to implement the 1993 NIH Revitalization Act and conducted extensive training for scientists and reviewers;
- the review process for extramural research treats the inclusion of women and minorities as a matter of scientific merit, affecting a proposal's eligibility for funding;
- the intramural research program now implements the inclusion policy;
- NIH maintains a centralized inclusion tracking data system which serves as a tool for monitoring the implementation of the inclusion policy; and
- in fiscal year 1997, more that 62% of participants in NIH-funded clinical research studies were women; minority women were also well represented, however, the proportion of Hispanic women enrolled was below their proportion in the general population.

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

- that the requirement be implemented that Phase III clinical trials be designed and carried out to allow for the valid analysis of differences between women and men and communicate this requirement to applicants as well as requiring peer review groups to determine whether each proposed Phase III clinical trial is required to have such a study design, and that summary statements document the decision of the initial reviewers; and
- that the NIH staff who transmit data to the inclusion tracking data system receive ongoing training on the requirements and purpose of the system.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Major changes have been made to the Population tracking system to help NIH staff in monitoring compliance with the NIH Inclusion policy. For example, the Population Tracking Grant Snapshot report was revised to provide easy access for NIH staff to the population data. Additionally, several Population Inclusion reports were added to the NIH Query View Report (QVR) system, thus providing broader access to the data. As well, user roles were revised and expanded to all the Division of Extramural Activities Support (DEAS) staff to assist in the data entry functions. The NIH Population Tracking Module for NIH staff was converted into a web-based application for easier access by NIH staff, with extensive participation and testing by module users, and the number of users has increased.

Communication and Outreach Efforts to the Scientific Community

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

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

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

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

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

Monitoring Compliance: Extramural and Intramural Population Data Analysis

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

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

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

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

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

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

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

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

Conclusion and Current Status

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

References

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

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

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

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

5. Hayunga, E.G., Costello, M.D. Pinn, V.W., Demographics of Study Populations, *Applied Clinical Trials*, Vol. 6, No.1, p. 41-45, 1997.

6. Hayunga, E.G. and Pinn V.W., Implementing the 1994 NIH Guidelines, *Applied Clinical Trials*, Vol. 5, No.10, p. 34-40, 1996.

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9. McCarthy, C.R., Historical Background of Clinical Trials Involving Women and Minorities, *Academic Medicine*, Vol. 69, No.9, p. 695-698, 1994.

10. Pinn, V.W., The Role of the NIH's Office of Research on Women's Health, *Academic Medicine,* Vol. 69, No. 9, p. 698-702, 1994.

11. Gallin, J, (2002). Principles and Practices of Clinical Research: Chapter 11 NIH Policy on the Inclusion of Women and Minorities as Subjects of Clinical Research, Academic Press, San Diego, California, pp 146-157.

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

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

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

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

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

Appendix B

Explanation of Sex and Minority Codes

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

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

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

Appendix C

NIH Tracking and Inclusion Committee Members

- Full Committee

NIH Tracking and Inclusion Committee
2008-2009 List of Members

Office of the Director

Office of Research on Women's Health

Vivian Pinn (Co-Chair), Angela Bates, Janine Smith, Indira Jevaji, Charles Wells

Office of Extramural Research

Robin Wagner*, Israel Lederhendler, Katrina Pearson, Maria Koshy, Svetlana Diggs, Lakshmi Kompella, Michael Goodman, Mark Siegert

Office of Acquisition, Management and Procurement

Rosemary Hamill, David Redd*

National Cancer Institute

Gail Blaufarb*, Kim Witherspoon, Clarissa Douglass

National Eye Institute

Donald Everett*, William Darby

National Heart, Lung, and Blood Institute

Carl Roth (Co-Chair)*, Sharry Palagi, Barbara Marzetta

National Human Genome Research Institute

Joy Boyer*

National Institute on Aging

Robin Barr*, Karen Bashir, Nina Silverberg, Marilyn Miller

National Institute on Alcohol Abuse and Alcoholism

Van Van*, Patricia Powell

National Institute of Allergy and Infectious Diseases

Diane Adger-Johnson*, Susan Schafer, Diane Yerg, Martin Gutierrez

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Shahnaz Khan*, Frank Cromwell, Ann Nicholson

National Institute of Child Health and Human Development

Eugene Hayunga*, Sandi Delcore

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

List of Members, continued...

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

National Institute of Dental and Craniofacial Research
Trenita Davis*

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

National Institute on Drug Addiction
Christie Espinosa*, Quandra Scudder

National Institute of Environmental Health Sciences
Martha Barnes*

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

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

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

National Institute of Nursing Research
Paul Cotton*, Angela Marshall

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

Warren G. Magnuson Clinical Center
Kim Jarema*, Theresa Doged

National Center for Complementary and Alternative Medicine
April Bower*

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

List of Members, continued...

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

Fogarty International Center
Aron Primack*, Francine Hill

Center for Scientific Review
Joy Gibson*

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

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

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

Appendix D

Internet Homepage:

Inclusion of Women and Minorities Policy Implementation

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

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

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

Current Policy Documents and References:

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

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

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

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

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

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

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

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

Historical Documents and References:

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

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

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

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

Appendix E

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

(Amended, October, 2001)

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

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

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

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

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

I. LEGISLATIVE BACKGROUND

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

The statute states that:

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

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

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

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

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

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

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

The statute speaks specifically to outreach and states that:

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

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

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

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

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

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

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

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

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

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

II. POLICY

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

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

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

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

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

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

1. Prior Studies Support the Existence of Significant Differences

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

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

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

2. Prior Studies Support No Significant Differences

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

3. Prior Studies Neither Support nor Negate Significant Differences

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

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

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

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

III. ROLES AND RESPONSIBILITIES

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

1. NIH Staff

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

2. Principal Investigators

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

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

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

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

3. Institutional Review Boards (IRBs)

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

4. Peer Review Groups

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

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

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

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

Or contact:

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

5. NIH Advisory Councils

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

6. Institute/Center Directors

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

7. NIH Director

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

IV. DEFINITIONS

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

A. Clinical Research

Clinical research is defined as:

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

B. NIH-defined Clinical Trial

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

C. Valid Analysis

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

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

D. Significant Difference

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

E. Racial and Ethnic Categories

1. Minority Groups

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

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

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

The following definitions apply for ethnic categories.

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

Not Hispanic or Latino

The following definitions apply for racial categories.

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

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

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

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

2. Majority Group

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

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

3. Subpopulations

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

F. Outreach Strategies

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

V. NIH CONTACTS FOR MORE INFORMATION

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

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Appendix F

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

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

Release Date: August 8, 2001

NOTICE: NOT-OD-01-053

National Institutes of Health

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

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

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

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

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

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

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

Ethnic Categories:

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

Not Hispanic or Latino

Racial Categories:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Annual Progress Reports (type 5) and Competing Supplement Applications

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

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

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

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

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

III. Frequently Asked Questions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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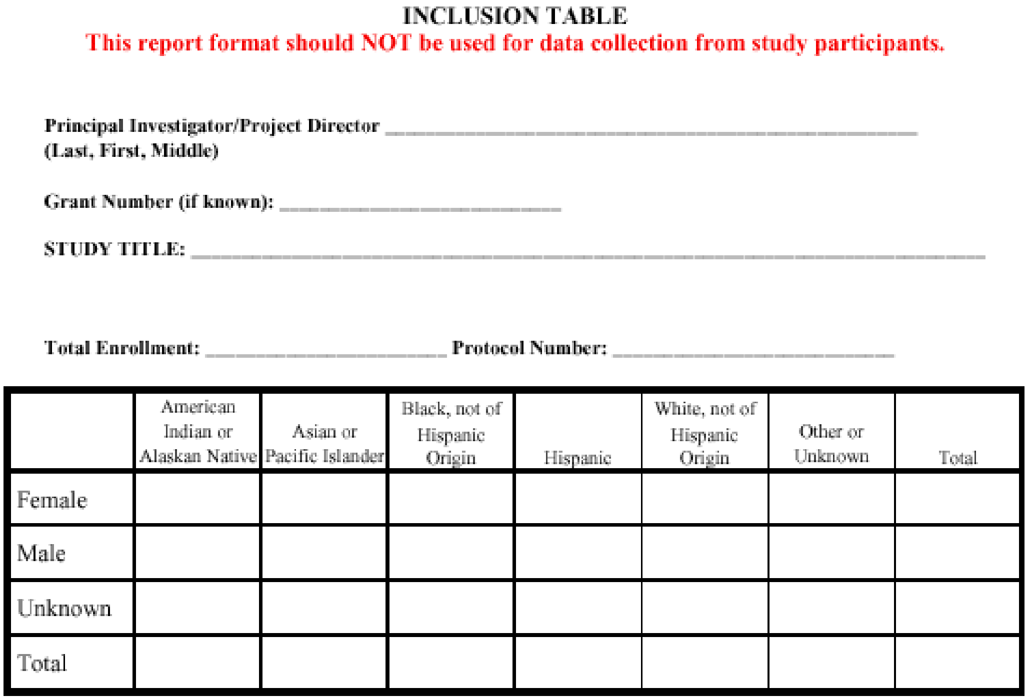
APPENDIX G

NIH Inclusion Tables for Target and Enrollment Data

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

Old Table for Target & Enrollment Data Collection



INCLUSION TABLE

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

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

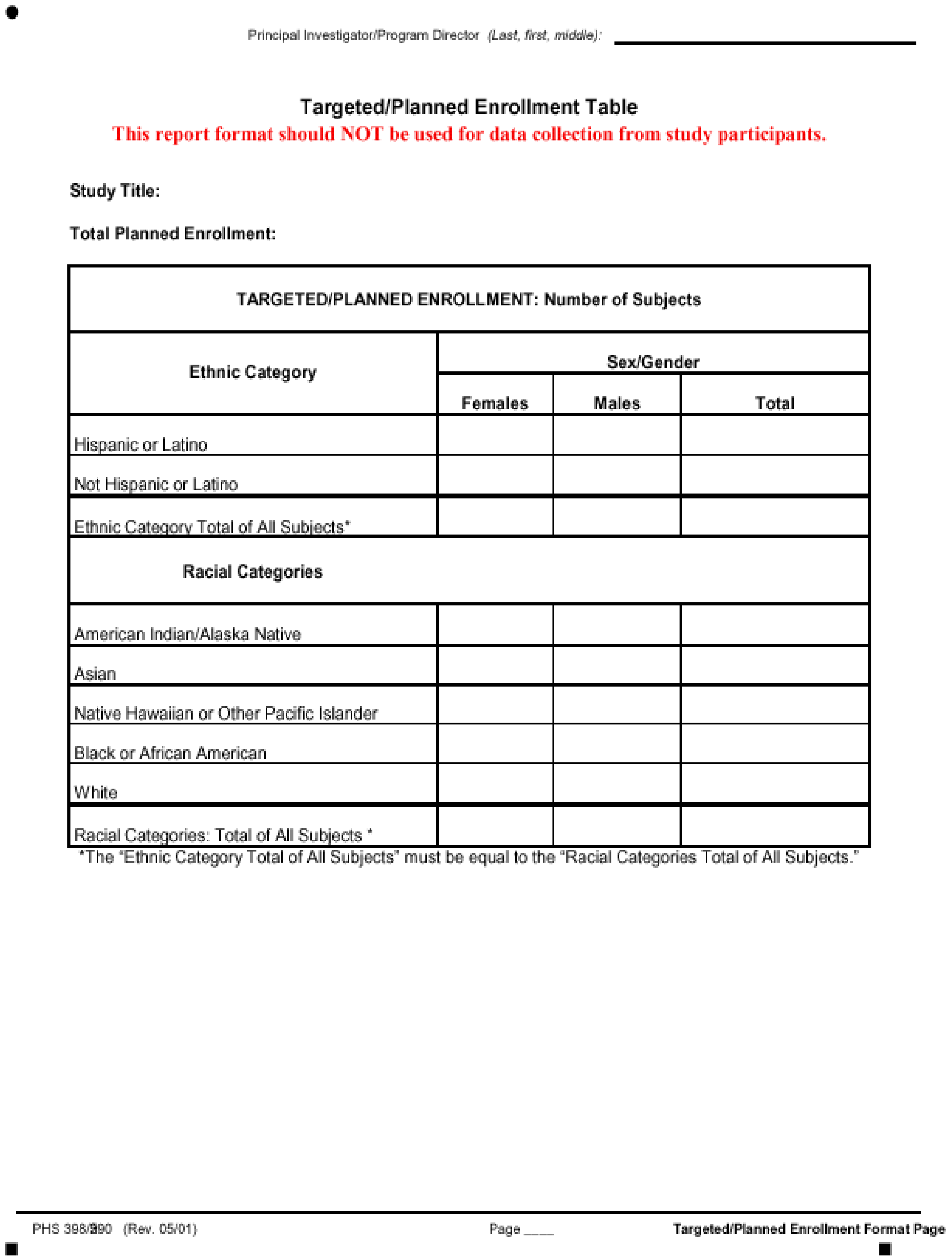
Grant Number (if known): ______________________

STUDY TITLE: ____

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

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

New Table for Target Data Collection



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

Targeted/Planned Enrollment Table

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

Study Title:

Total Planned Enrollment:

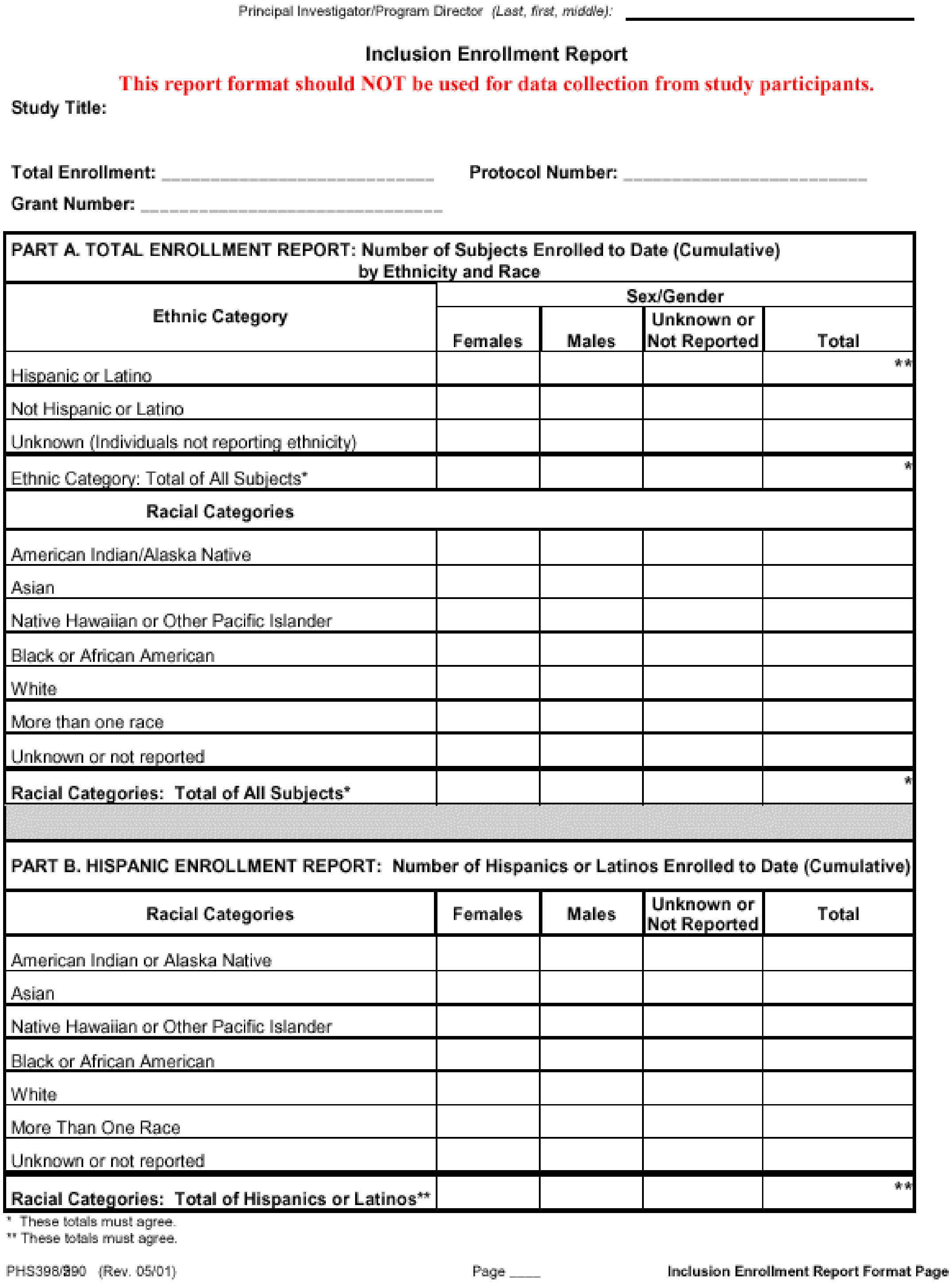
TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total of All Subjects*			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander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

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

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

New Table for Enrollment Data Collection

-



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

Inclusion Enrollment Report

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

Study Title:

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

Grant Number: ______________________

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

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

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

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

* These totals must agree.

** These totals must agree.

PHS398/2590 (Rev. 05/01) Page ____ **Inclusion Enrollment Report Format Page**

Appendix H

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

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

CLINICAL RESEARCH: NIH defines human clinical research as:

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

(2) Epidemiologic and behavioral studies.

(3) Outcomes research and health services research.

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

OLD FORM (1977) versus NEW FORM (1997)

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

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

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

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

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

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

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

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

Appendix I

Aggregate Extramural and Intramural Data Tables Funded in FY2008 and Reported in FY2009

Table of Contents: Fiscal Year 2009 Aggregate Data Tables

<u>Domestic and Foreign Clinical Research Reported in FY 2008 and 2009</u>

Table 1A. Aggregate Enrollment Data for Extramural and Intramural Research Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	**Total Enrollment**	**Minority Enrollment**	**Total % Minority**	**% Minority by Sex**
Females	**11,439,143**	**3,438,992**		**30.06%**
%	**59.77%**	**59.46%**		
Males	**7,570,646**	**2,325,402**		**30.72%**
%	**39.56%**	**40.21%**		
Unknown	**128,949**	**19,149**		**14.85%**
%	**0.67%**	**0.33%**		
TOTAL	**19,138,738**	**5,783,543**	**30.22%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**11,171**

Number of Protocols with Enrollment Data: 10,328

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards												
	Total of All Subjects by Race								**Total of All Subjects by Ethnicity**			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	101,463	1,266,696	1,146,190	30,035	7,679,462	187,251	819,745	11,230,842	9,625,641	789,940	815,261	11,230,842
	0.54%	**6.76%**	**6.11%**	**0.16%**	**40.96%**	**1.00%**	**4.37%**	**59.90%**	**51.34%**	**4.21%**	**4.35%**	**59.90%**
	0.90%	*11.28%*	*10.21%*	*0.27%*	*68.38%*	*1.67%*	*7.30%*	*100.00%*	*85.71%*	*7.03%*	*7.26%*	*100.00%*
	65.67%	68.82%	50.10%	59.67%	60.04%	57.82%	62.98%	59.90%	60.03%	60.63%	57.71%	59.90%
Male	52,475	572,087	1,129,740	20,181	5,092,116	135,211	387,859	7,389,669	6,376,522	508,385	504,762	7,389,669
	0.28%	**3.05%**	**6.03%**	**0.11%**	**27.16%**	**0.72%**	2.07%	**39.41%**	**34.01%**	**2.71%**	**2.69%**	**39.41%**
	0.71%	*7.74%*	*15.29%*	*0.27%*	*68.91%*	*1.83%*	5.25%	*100.00%*	*86.29%*	*6.88%*	*6.83%*	*100.00%*
	33.96%	31.08%	49.39%	40.09%	39.81%	41.75%	29.80%	39.41%	39.77%	39.02%	35.73%	39.41%
Unknown	577	1,756	11,647	123	19,367	1,377	93,914	128,761	31,384	4,619	92,758	128,761
	0.00%	**0.01%**	**0.06%**	0.00%	**0.10%**	**0.01%**	***0.50%***	**0.69%**	**0.17%**	**0.02%**	**0.49%**	**0.69%**
	0.45%	*1.36%*	*9.05%*	0.10%	*15.04%*	*1.07%*	*72.94%*	*100.00%*	*24.37%*	*3.59%*	*72.04%*	*100.00%*
	0.37%	0.10%	0.51%	0.24%	0.15%	0.43%	7.22%	0.69%	0.20%	0.35%	6.57%	0.69%
Total	154,515	1,840,539	2,287,577	50,339	12,790,945	323,839	1,301,518	18,749,272	16,033,547	1,302,944	1,412,781	18,749,272
	0.82%	**9.82%**	**12.20%**	**0.27%**	**68.22%**	**1.73%**	**6.94%**	**100.00%**	**85.52%**	**6.95%**	**7.54%**	**100.00%**
	0.82%	*9.82%*	*12.20%*	*0.27%*	*68.22%*	*1.73%*	*6.94%*	*100.00%*	*85.52%*	*6.95%*	*7.54%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	22,979	29,030	30,344	1,760	456,298	36,597	212,950	789,958	3,400,883
%	**1.76%**	**2.23%**	**2.33%**	**0.14%**	**35.02%**	**2.81%**	**16.34%**	**60.62%**	**18.14%**
	2.91%	*3.67%*	*3.84%*	*0.22%*	*57.76%*	*4.63%*	*26.96%*	*100.00%*	*30.28%*
	58.62%	54.22%	33.28%	56.72%	62.56%	57.24%	65.97%	60.62%	59.57%
Male	16,050	24,387	60,274	1305	272,237	27,282	107,016	508,551	2,288,947
%	**1.23%**	**1.87%**	**4.63%**	**0.10%**	**20.89%**	**2.09%**	**8.21%**	**39.03%**	**12.21%**
	3.16%	*4.80%*	*11.85%*	*0.26%*	*53.53%*	*5.36%*	*21.04%*	*100.00%*	*30.97%*
	40.95%	45.54%	66.10%	42.06%	37.33%	42.67%	33.15%	39.03%	40.09%
Unknown	169	129	566	38	820	55	2,842	4,619	19,142
%	**0.01%**	**0.01%**	**0.04%**	**0.00%**	**0.06%**	**0.00%**	**0.22%**	**0.35%**	**0.10%**
	3.66%	*2.79%*	*12.25%*	*0.82%*	*17.75%*	*1.19%*	*61.53%*	*100.00%*	*14.87%*
	0.43%	0.24%	0.62%	1.22%	0.11%	0.09%	0.88%	0.35%	0.34%
TOTAL	39,198	53,546	91,184	3,103	729,355	63,934	322,808	1,303,128	5,708,972
	3.01%	**4.11%**	**7.00%**	**0.24%**	**55.97%**	**4.91%**	**24.77%**	**100.00%**	**30.45%**
	3.01%	*4.11%*	*7.00%*	*0.24%*	*55.97%*	*4.91%*	*24.77%*	*100.00%*	*30.45%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 1C

Number of Protocols with Enrollment Data:	**843**

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

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	720	6,456	21,105	9,828	162,192	8,000	208,301	38,109
	0.18%	**1.66%**	**5.42%**	**2.52%**	**41.64%**	**2.05%**	**53.48%**	**9.78%**
	0.35%	*3.10%*	*10.13%*	*4.72%*	*77.86%*	*3.84%*	*100.00%*	*18.30%*
	59.36%	55.41%	49.77%	50.92%	54.22%	50.70%	53.48%	51.10%
Male	493	5,194	21,297	9,471	136,893	7,629	180,977	36,455
	0.13%	**1.33%**	**5.47%**	**2.43%**	**35.15%**	**1.96%**	**46.47%**	**9.36%**
	0.27%	*2.87%*	*11.77%*	*5.23%*	*75.64%*	*4.22%*	*100.00%*	*20.14%*
	40.64%	44.58%	50.22%	49.07%	45.77%	48.35%	46.47%	48.89%
Unknown	0	2	3	2	30	151	188	7
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.04%**	**0.05%**	**0.00%**
	0.00%	*1.06%*	*1.60%*	*1.06%*	*15.96%*	*80.32%*	*100.00%*	*3.72%*
	0.00%	0.02%	0.01%	0.01%	0.01%	0.96%	0.05%	0.01%
Total	1,213	11,652	42,405	19,301	299,115	15,780	389,466	74,571
	0.31%	**2.99%**	**10.89%**	**4.96%**	**76.80%**	**4.05%**	**100.00%**	**19.15%**
	0.31%	*2.99%*	*10.89%*	*4.96%*	*76.80%*	*4.05%*	*100.00%*	*19.15%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 2A. Aggregate Enrollment Data for Extramural and Intramural Phase III Research Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	630

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

Number of Protocols with Enrollment Data:	434

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	9,875	47,848	61,823	438	107,105	2,283	23,530	252,902	210,945	34,357	7,600	252,902
	2.03%	9.83%	12.71%	0.09%	22.01%	0.47%	4.84%	51.98%	43.35%	7.06%	1.56%	51.98%
	3.90%	18.92%	24.45%	0.17%	42.35%	0.90%	9.30%	100.00%	83.41%	13.59%	3.01%	100.00%
	56.40%	51.52%	53.19%	50.99%	56.51%	48.82%	36.26%	51.98%	53.81%	65.79%	17.95%	51.98%
Male	7,575	44,912	54,229	417	81,253	2,334	12,585	203,305	179,583	17,487	6,235	203,305
	1.56%	9.23%	11.15%	0.09%	16.70%	0.48%	2.59%	41.78%	36.91%	3.59%	1.28%	41.78%
	3.73%	22.09%	26.67%	0.21%	39.97%	1.15%	6.19%	100.00%	88.33%	8.60%	3.07%	100.00%
	43.26%	48.36%	46.66%	48.54%	42.87%	49.91%	19.39%	41.78%	45.81%	33.49%	14.72%	41.78%
Unknown	59	108	181	4	1,169	59	28,776	30,356	1,462	379	28,515	30,356
	0.01%	0.02%	0.04%	0.00%	0.24%	0.01%	5.91%	6.24%	0.30%	0.08%	5.86%	6.24%
	0.19%	0.36%	0.60%	0.01%	3.85%	0.19%	94.80%	100.00%	4.82%	1.25%	93.94%	100.00%
	0.34%	0.12%	0.16%	0.47%	0.62%	1.26%	44.35%	6.24%	0.37%	0.73%	67.33%	6.24%
Total	17,509	92,868	116,233	859	189,527	4,676	64,891	486,563	391,990	52,223	42,350	486,563
	3.60%	19.09%	23.89%	0.18%	38.95%	0.96%	13.34%	100.00%	80.56%	10.73%	8.70%	100.00%
	3.60%	19.09%	23.89%	0.18%	38.95%	0.96%	13.34%	100.00%	80.56%	10.73%	8.70%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female %	8,729	138	488	99	7,265	431	17,207	34,357	146,739
	16.71%	0.26%	0.93%	0.19%	13.91%	0.83%	32.95%	65.79%	30.16%
	25.41%	0.40%	1.42%	0.29%	21.15%	1.25%	50.08%	100.00%	58.02%
	57.00%	39.32%	52.08%	50.00%	63.25%	44.71%	74.90%	65.79%	55.04%
Male %	6,543	203	439	95	4,160	521	5,526	17,487	119,153
	12.53%	0.39%	0.84%	0.18%	7.97%	1.00%	10.58%	33.49%	24.49%
	37.42%	1.16%	2.51%	0.54%	23.79%	2.98%	31.60%	100.00%	58.61%
	42.73%	57.83%	46.85%	47.98%	36.21%	54.05%	24.05%	33.49%	44.69%
Unknown %	41	10	10	4	62	12	240	379	713
	0.08%	0.02%	0.02%	0.01%	0.12%	0.02%	0.46%	0.73%	0.15%
	10.82%	2.64%	2.64%	1.06%	16.36%	3.17%	63.32%	100.00%	2.35%
	0.27%	2.85%	1.07%	2.02%	0.54%	1.24%	1.04%	0.73%	0.27%
TOTAL	15,313	351	937	198	11,487	964	22,973	52,223	266,605
	29.32%	0.67%	1.79%	0.38%	22.00%	1.85%	43.99%	100.00%	54.79%
	29.32%	0.67%	1.79%	0.38%	22.00%	1.85%	43.99%	100.00%	54.79%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 2C

Number of Protocols with Enrollment Data:	196

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

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

Legend

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

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

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

Table 3A. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	9,444

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

Number of Protocols with Enrollment Data: 8,993

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	91,643	1,090,555	1,073,690	29,381	6,939,461	108,399	728,852	10,061,981	8,658,138	728,314	675,529	10,061,981
	0.57%	6.83%	6.73%	0.18%	43.48%	0.68%	4.57%	63.05%	54.25%	4.56%	4.23%	63.05%
	0.91%	10.84%	10.67%	0.29%	68.97%	1.08%	7.24%	100.00%	86.05%	7.24%	6.71%	100.00%
	68.59%	69.82%	53.28%	60.09%	62.98%	63.37%	72.24%	63.05%	62.89%	61.08%	67.56%	63.05%
Male	41,411	469,956	933,867	19,392	4,072,005	61,291	215,172	5,813,094	5,093,038	459,455	260,601	5,813,094
	0.26%	2.94%	5.85%	0.12%	25.52%	0.38%	1.35%	36.43%	31.91%	2.88%	1.63%	36.43%
	0.71%	8.08%	16.06%	0.33%	70.05%	1.05%	3.70%	100.00%	87.61%	7.90%	4.48%	100.00%
	30.99%	30.09%	46.34%	39.66%	36.95%	35.83%	21.33%	36.43%	36.99%	38.53%	26.06%	36.43%
Unknown	553	1,387	7,798	123	7,831	1,358	64,951	84,001	15,669	4,596	63,736	84,001
	0.00%	0.01%	0.05%	0.00%	0.05%	0.01%	0.41%	0.53%	0.10%	0.03%	0.40%	0.53%
	0.66%	1.65%	9.28%	0.15%	9.32%	1.62%	77.32%	100.00%	18.65%	5.47%	75.88%	100.00%
	0.41%	0.09%	0.39%	0.25%	0.07%	0.79%	6.44%	0.53%	0.11%	0.39%	6.37%	0.53%
Total	133,607	1,561,898	2,015,355	48,896	11,019,297	171,048	1,008,975	15,959,076	13,766,845	1,192,365	999,866	15,959,076
	0.84%	9.79%	12.63%	0.31%	69.05%	1.07%	6.32%	100.00%	86.26%	7.47%	6.27%	100.00%
	0.84%	9.79%	12.63%	0.31%	69.05%	1.07%	6.32%	100.00%	86.26%	7.47%	6.27%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	22,861	28,987	29,538	1,701	427,774	33,373	184,098	728,332	3,005,540
%	1.92%	2.43%	2.48%	0.14%	35.87%	2.80%	15.44%	61.07%	18.83%
	3.14%	3.98%	4.06%	0.23%	58.73%	4.58%	25.28%	100.00%	29.87%
	58.60%	54.22%	33.76%	56.53%	63.93%	57.90%	65.09%	61.07%	61.55%
Male	15,986	24,346	57,394	1270	240,495	24,228	95,902	459,621	1,862,314
%	1.34%	2.04%	4.81%	0.11%	20.17%	2.03%	8.04%	38.54%	11.67%
	3.48%	5.30%	12.49%	0.28%	52.32%	5.27%	20.87%	100.00%	32.04%
	40.97%	45.54%	65.59%	42.21%	35.94%	42.03%	33.91%	38.54%	38.14%
Unknown	168	129	566	38	820	39	2,836	4,596	14,875
%	0.01%	0.01%	0.05%	0.00%	0.07%	0.00%	0.24%	0.39%	0.09%
	3.66%	2.81%	12.32%	0.83%	17.84%	0.85%	61.71%	100.00%	17.71%
	0.43%	0.24%	0.65%	1.26%	0.12%	0.07%	1.00%	0.39%	0.30%
TOTAL	39,015	53,462	87,498	3,009	669,089	57,640	282,836	1,192,549	4,882,729
	3.27%	4.48%	7.34%	0.25%	56.11%	4.83%	23.72%	100.00%	30.60%
	3.27%	4.48%	7.34%	0.25%	56.11%	4.83%	23.72%	100.00%	30.60%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 3C

Number of Protocols with Enrollment Data: **451**

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

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

Legend

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

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

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

Table 4A. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male_Only and Female-Only Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	7,707

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

Number of Protocols with Enrollment Data: 7,404

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	44,382	433,527	816,068	26,622	4,011,827	75,247	226,437	5,634,110	4,980,970	449,485	203,655	5,634,110
	0.40%	**3.87%**	**7.28%**	**0.24%**	**35.77%**	**0.67%**	**2.02%**	**50.23%**	**44.41%**	**4.01%**	**1.82%**	**50.23%**
	0.79%	*7.69%*	*14.48%*	*0.47%*	*71.21%*	*1.34%*	*4.02%*	*100.00%*	*88.41%*	*7.98%*	*3.61%*	*100.00%*
	51.75%	52.20%	47.38%	57.97%	50.82%	55.27%	45.23%	50.23%	50.55%	49.79%	44.38%	50.23%
Male	40,828	395,569	898,353	19,179	3,875,190	59,547	209,270	5,497,936	4,857,833	448,637	191,466	5,497,936
	0.36%	**3.53%**	**8.01%**	**0.17%**	**34.55%**	**0.53%**	1.87%	**49.02%**	**43.31%**	**4.00%**	**1.71%**	**49.02%**
	0.74%	*7.19%*	*16.34%*	*0.35%*	*70.48%*	*1.08%*	3.81%	*100.00%*	*88.36%*	*8.16%*	*3.48%*	*100.00%*
	47.61%	47.63%	52.16%	41.76%	49.09%	43.74%	41.80%	49.02%	49.30%	49.70%	41.73%	49.02%
Unknown	553	1,387	7,798	123	7,831	1,358	64,951	84,001	15,669	4,596	63,736	84,001
	0.00%	**0.01%**	**0.07%**	0.00%	**0.07%**	**0.01%**	***0.58%***	**0.75%**	**0.14%**	**0.04%**	**0.57%**	**0.75%**
	0.66%	*1.65%*	*9.28%*	0.15%	*9.32%*	*1.62%*	*77.32%*	*100.00%*	*18.65%*	*5.47%*	*75.88%*	*100.00%*
	0.64%	0.17%	0.45%	0.27%	0.10%	1.00%	12.97%	0.75%	0.16%	0.51%	13.89%	0.75%
Total	85,763	830,483	1,722,219	45,924	7,894,848	136,152	500,658	11,216,047	9,854,472	902,718	458,857	11,216,047
	0.76%	**7.40%**	**15.35%**	**0.41%**	**70.39%**	**1.21%**	**4.46%**	**100.00%**	**87.86%**	**8.05%**	**4.09%**	**100.00%**
	0.76%	*7.40%*	*15.35%*	*0.41%*	*70.39%*	*1.21%*	*4.46%*	*100.00%*	*87.86%*	*8.05%*	*4.09%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	16,377	25,246	25,141	1,408	259,664	25,744	95,923	449,503	1,751,433
%	**1.81%**	**2.80%**	**2.78%**	**0.16%**	**28.76%**	**2.85%**	**10.62%**	**49.78%**	**15.62%**
	3.64%	*5.62%*	*5.59%*	*0.31%*	*57.77%*	*5.73%*	*21.34%*	*100.00%*	*31.09%*
	50.72%	50.80%	30.49%	52.13%	52.10%	54.81%	50.37%	49.78%	49.91%
Male	15,741	24,322	56,761	1255	237,869	21,183	91,672	448,803	1,743,017
%	**1.74%**	**2.69%**	**6.29%**	**0.14%**	**26.34%**	**2.35%**	**10.15%**	**49.71%**	**15.54%**
	3.51%	*5.42%*	*12.65%*	*0.28%*	*53.00%*	*4.72%*	*20.43%*	*100.00%*	*31.70%*
	48.75%	48.94%	68.83%	46.46%	47.73%	45.10%	48.14%	49.71%	49.67%
Unknown	168	129	566	38	820	39	2,836	4,596	14,875
%	**0.02%**	**0.01%**	**0.06%**	**0.00%**	**0.09%**	**0.00%**	**0.31%**	**0.51%**	**0.13%**
	3.66%	*2.81%*	*12.32%*	*0.83%*	*17.84%*	*0.85%*	*61.71%*	*100.00%*	*17.71%*
	0.52%	0.26%	0.69%	1.41%	0.16%	0.08%	1.49%	0.51%	0.42%
TOTAL	32,286	49,697	82,468	2,701	498,353	46,966	190,431	902,902	3,509,325
	3.58%	**5.50%**	**9.13%**	**0.30%**	**55.19%**	**5.20%**	**21.09%**	**100.00%**	**31.29%**
	3.58%	*5.50%*	*9.13%*	*0.30%*	*55.19%*	*5.20%*	*21.09%*	*100.00%*	*31.29%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 4C

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

Number of Protocols with Enrollment Data: **303**

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

Legend

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

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

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

Table 5A. Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	**592**

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

Number of Protocols with Enrollment Data: 407

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	9,746	47,842	61,229	438	106,737	2,281	14,361	242,634	209,663	26,804	6,167	242,634
	2.06%	**10.11%**	**12.94%**	**0.09%**	**22.56%**	**0.48%**	**3.04%**	**51.28%**	**44.31%**	**5.67%**	**1.30%**	**51.28%**
	4.02%	*19.72%*	*25.24%*	*0.18%*	*43.99%*	*0.94%*	*5.92%*	*100.00%*	*86.41%*	*11.05%*	*2.54%*	*100.00%*
	56.23%	51.53%	53.13%	51.05%	56.50%	48.82%	26.96%	51.28%	53.85%	60.18%	15.72%	51.28%
Male	7,528	44,893	53,855	416	80,993	2,332	10,134	200,151	178,242	17,354	4,555	200,151
	1.59%	**9.49%**	**11.38%**	**0.09%**	**17.12%**	**0.49%**	2.14%	**42.30%**	**37.67%**	**3.67%**	**0.96%**	**42.30%**
	3.76%	*22.43%*	*26.91%*	*0.21%*	*40.47%*	*1.17%*	5.06%	*100.00%*	*89.05%*	*8.67%*	*2.28%*	*100.00%*
	43.43%	48.35%	46.73%	48.48%	42.88%	49.91%	19.02%	42.30%	45.78%	38.97%	11.61%	42.30%
Unknown	59	108	168	4	1,169	59	28,776	30,343	1,449	379	28,515	30,343
	0.01%	**0.02%**	**0.04%**	0.00%	**0.25%**	**0.01%**	*6.08%*	**6.41%**	**0.31%**	**0.08%**	**6.03%**	**6.41%**
	0.19%	*0.36%*	*0.55%*	0.01%	*3.85%*	*0.19%*	*94.84%*	*100.00%*	*4.78%*	*1.25%*	*93.98%*	*100.00%*
	0.34%	0.12%	0.15%	0.47%	0.62%	1.26%	54.02%	6.41%	0.37%	0.85%	72.67%	6.41%
Total	17,333	92,843	115,252	858	188,899	4,672	53,271	473,128	389,354	44,537	39,237	473,128
	3.66%	**19.62%**	**24.36%**	**0.18%**	**39.93%**	**0.99%**	**11.26%**	**100.00%**	**82.29%**	**9.41%**	**8.29%**	**100.00%**
	3.66%	*19.62%*	*24.36%*	*0.18%*	*39.93%*	*0.99%*	*11.26%*	*100.00%*	*82.29%*	*9.41%*	*8.29%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	8,728	138	488	99	7,263	431	9,657	26,804	138,456
%	**19.60%**	**0.31%**	**1.10%**	**0.22%**	**16.31%**	**0.97%**	**21.68%**	**60.18%**	**29.26%**
	32.56%	*0.51%*	*1.82%*	*0.37%*	*27.10%*	*1.61%*	*36.03%*	*100.00%*	*57.06%*
	57.00%	39.32%	52.08%	50.00%	63.24%	44.71%	63.15%	60.18%	53.72%
Male	6,543	203	439	95	4,159	521	5,394	17,354	118,577
%	**14.69%**	**0.46%**	**0.99%**	**0.21%**	**9.34%**	**1.17%**	**12.11%**	**38.97%**	**25.06%**
	37.70%	*1.17%*	*2.53%*	*0.55%*	*23.97%*	*3.00%*	*31.08%*	*100.00%*	*59.24%*
	42.73%	57.83%	46.85%	47.98%	36.22%	54.05%	35.28%	38.97%	46.01%
Unknown	41	10	10	4	62	12	240	379	700
%	**0.09%**	**0.02%**	**0.02%**	**0.01%**	**0.14%**	**0.03%**	**0.54%**	**0.85%**	**0.15%**
	10.82%	*2.64%*	*2.64%*	*1.06%*	*16.36%*	*3.17%*	*63.32%*	*100.00%*	*2.31%*
	0.27%	2.85%	1.07%	2.02%	0.54%	1.24%	1.57%	0.85%	0.27%
TOTAL	15,312	351	937	198	11,484	964	15,291	44,537	257,733
	34.38%	**0.79%**	**2.10%**	**0.44%**	**25.79%**	**2.16%**	**34.33%**	**100.00%**	**54.47%**
	34.38%	*0.79%*	*2.10%*	*0.44%*	*25.79%*	*2.16%*	*34.33%*	*100.00%*	*54.47%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 5C

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

Number of Protocols with Enrollment Data: **185**

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

Legend

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

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

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

Table 6A. Aggregate Enrollment Data for Extramural Phase III Research Protocols, Excluding Male-Only and Female-Only Protocols, Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**200,008**	**114,445**		**57.22%**
%	**45.87%**	**48.52%**		
Males	**205,655**	**120,747**		**58.71%**
%	**47.16%**	**51.19%**		
Unknown	**30,380**	**702**		**2.31%**
%	**6.97%**	**0.30%**		
TOTAL	**436,043**	**235,894**	**54.10%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**398**

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

Number of Protocols with Enrollment Data: 296

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	7,313	40,337	52,618	291	64,527	2,080	9,068	176,234	156,098	15,756	4,380	176,234
	1.89%	**10.45%**	**13.63%**	**0.08%**	**16.71%**	**0.54%**	**2.35%**	**45.64%**	**40.43%**	**4.08%**	**1.13%**	**45.64%**
	4.15%	*22.89%*	*29.86%*	*0.17%*	*36.61%*	*1.18%*	*5.15%*	*100.00%*	*88.57%*	*8.94%*	*2.49%*	*100.00%*
	49.18%	47.72%	49.78%	41.51%	50.21%	47.03%	19.14%	45.64%	49.40%	47.85%	11.77%	45.64%
Male	7,498	44,092	52,907	406	62,810	2,284	9,536	179,533	158,409	16,794	4,330	179,533
	1.94%	**11.42%**	**13.70%**	**0.11%**	**16.27%**	**0.59%**	2.47%	**46.50%**	**41.03%**	**4.35%**	**1.12%**	**46.50%**
	4.18%	*24.56%*	*29.47%*	*0.23%*	*34.99%*	*1.27%*	5.31%	*100.00%*	*88.23%*	*9.35%*	*2.41%*	*100.00%*
	50.42%	52.16%	50.06%	57.92%	48.88%	51.64%	20.13%	46.50%	50.14%	51.00%	11.63%	46.50%
Unknown	59	108	168	4	1,169	59	28,776	30,343	1,449	379	28,515	30,343
	0.02%	**0.03%**	**0.04%**	0.00%	**0.30%**	**0.02%**	*7.45%*	**7.86%**	**0.38%**	**0.10%**	**7.39%**	**7.86%**
	0.19%	*0.36%*	*0.55%*	0.01%	*3.85%*	*0.19%*	*94.84%*	*100.00%*	*4.78%*	*1.25%*	*93.98%*	*100.00%*
	0.40%	0.13%	0.16%	0.57%	0.91%	1.33%	60.73%	7.86%	0.46%	1.15%	76.60%	7.86%
Total	14,870	84,537	105,693	701	128,506	4,423	47,380	386,110	315,956	32,929	37,225	386,110
	3.85%	**21.89%**	**27.37%**	**0.18%**	**33.28%**	**1.15%**	**12.27%**	**100.00%**	**81.83%**	**8.53%**	**9.64%**	**100.00%**
	3.85%	*21.89%*	*27.37%*	*0.18%*	*33.28%*	*1.15%*	*12.27%*	*100.00%*	*81.83%*	*8.53%*	*9.64%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	6,465	123	313	81	3,450	414	4,910	15,756	110,999
%	**19.63%**	**0.37%**	**0.95%**	**0.25%**	**10.48%**	**1.26%**	**14.91%**	**47.85%**	**28.75%**
	41.03%	*0.78%*	*1.99%*	*0.51%*	*21.90%*	*2.63%*	*31.16%*	*100.00%*	*62.98%*
	49.56%	36.61%	41.57%	45.25%	45.88%	43.72%	48.38%	47.85%	48.71%
Male	6,539	203	430	94	4,008	521	4,999	16,794	116,194
%	**19.86%**	**0.62%**	**1.31%**	**0.29%**	**12.17%**	**1.58%**	**15.18%**	**51.00%**	**30.09%**
	38.94%	*1.21%*	*2.56%*	*0.56%*	*23.87%*	*3.10%*	*29.77%*	*100.00%*	*64.72%*
	50.13%	60.42%	57.10%	52.51%	53.30%	55.02%	49.26%	51.00%	50.99%
Unknown	41	10	10	4	62	12	240	379	700
%	**0.12%**	**0.03%**	**0.03%**	**0.01%**	**0.19%**	**0.04%**	**0.73%**	**1.15%**	**0.18%**
	10.82%	*2.64%*	*2.64%*	*1.06%*	*16.36%*	*3.17%*	*63.32%*	*100.00%*	*2.31%*
	0.31%	2.98%	1.33%	2.23%	0.82%	1.27%	2.36%	1.15%	0.31%
TOTAL	13,045	336	753	179	7,520	947	10,149	32,929	227,893
	39.62%	**1.02%**	**2.29%**	**0.54%**	**22.84%**	**2.88%**	**30.82%**	**100.00%**	**59.02%**
	39.62%	*1.02%*	*2.29%*	*0.54%*	*22.84%*	*2.88%*	*30.82%*	*100.00%*	*59.02%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 6C

Number of Protocols with Enrollment Data: **102**

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

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	84	591	1,927	844	19,598	730	23,774	3,446
	0.17%	**1.18%**	**3.86%**	**1.69%**	**39.25%**	**1.46%**	**47.61%**	**6.90%**
	0.35%	*2.49%*	*8.11%*	*3.55%*	*82.43%*	*3.07%*	*100.00%*	*14.49%*
	43.98%	51.17%	42.95%	38.93%	48.64%	44.46%	47.61%	43.07%
Male	107	563	2,559	1,324	20,681	888	26,122	4,553
	0.21%	**1.13%**	**5.12%**	**2.65%**	**41.42%**	**1.78%**	**52.31%**	**9.12%**
	0.41%	*2.16%*	*9.80%*	*5.07%*	*79.17%*	*3.40%*	*100.00%*	*17.43%*
	56.02%	48.74%	57.03%	61.07%	51.33%	54.08%	52.31%	56.91%
Unknown	0	1	1	0	11	24	37	2
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.02%**	**0.05%**	**0.07%**	**0.00%**
	0.00%	*2.70%*	*2.70%*	*0.00%*	*29.73%*	*64.86%*	*100.00%*	*5.41%*
	0.00%	0.09%	0.02%	0.00%	0.03%	1.46%	0.07%	0.02%
Total	191	1,155	4,487	2,168	40,290	1,642	49,933	8,001
	0.38%	**2.31%**	**8.99%**	**4.34%**	**80.69%**	**3.29%**	**100.00%**	**16.02%**
	0.38%	*2.31%*	*8.99%*	*4.34%*	*80.69%*	*3.29%*	*100.00%*	*16.02%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 7. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	1,727

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

Number of Protocols with Enrollment Data: 1,335

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	9,820	176,141	72,500	654	740,001	78,852	90,893	1,168,861	967,503	61,626	139,732	1,168,861
	0.35%	6.31%	2.60%	0.02%	26.52%	2.83%	3.26%	41.89%	34.68%	2.21%	5.01%	41.89%
	0.84%	15.07%	6.20%	0.06%	63.31%	6.75%	7.78%	100.00%	82.77%	5.27%	11.95%	100.00%
	46.97%	63.21%	26.63%	45.32%	41.77%	51.61%	31.07%	41.89%	42.68%	55.73%	33.84%	41.89%
Male	11,064	102,131	195,873	789	1,020,111	73,920	172,687	1,576,575	1,283,484	48,930	244,161	1,576,575
	0.40%	3.66%	7.02%	0.03%	36.56%	2.65%	6.19%	56.50%	46.00%	1.75%	8.75%	56.50%
	0.70%	6.48%	12.42%	0.05%	64.70%	4.69%	10.95%	100.00%	81.41%	3.10%	15.49%	100.00%
	52.92%	36.65%	71.95%	54.68%	57.58%	48.38%	59.03%	56.50%	56.62%	44.25%	59.13%	56.50%
Unknown	24	369	3,849	0	11,536	19	28,963	44,760	15,715	23	29,022	44,760
	0.00%	0.01%	0.14%	0.00%	0.41%	0.00%	1.04%	1.60%	0.56%	0.00%	1.04%	1.60%
	0.05%	0.82%	8.60%	0.00%	25.77%	0.04%	64.71%	100.00%	35.11%	0.05%	64.84%	100.00%
	0.11%	0.13%	1.41%	0.00%	0.65%	0.01%	9.90%	1.60%	0.69%	0.02%	7.03%	1.60%
Total	20,908	278,641	272,222	1,443	1,771,648	152,791	292,543	2,790,196	2,266,702	110,579	412,915	2,790,196
	0.75%	9.99%	9.76%	0.05%	63.50%	5.48%	10.48%	100.00%	81.24%	3.96%	14.80%	100.00%
	0.75%	9.99%	9.76%	0.05%	63.50%	5.48%	10.48%	100.00%	81.24%	3.96%	14.80%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	118	43	806	59	28,524	3,224	28,852	61,626	395,343
%	0.11%	0.04%	0.73%	0.05%	25.80%	2.92%	26.09%	55.73%	14.17%
	0.19%	0.07%	1.31%	0.10%	46.29%	5.23%	46.82%	100.00%	33.82%
	64.48%	51.19%	21.87%	62.77%	47.33%	51.22%	72.18%	55.73%	47.85%
Male	64	41	2,880	35	31,742	3,054	11,114	48,930	426,633
%	0.06%	0.04%	2.60%	0.03%	28.71%	2.76%	10.05%	44.25%	15.29%
	0.13%	0.08%	5.89%	0.07%	64.87%	6.24%	22.71%	100.00%	27.06%
	34.97%	48.81%	78.13%	37.23%	52.67%	48.52%	27.80%	44.25%	51.64%
Unknown	1	0	0	0	0	16	6	23	4,267
%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.02%	0.15%
	4.35%	0.00%	0.00%	0.00%	0.00%	69.57%	26.09%	100.00%	9.53%
	0.55%	0.00%	0.00%	0.00%	0.00%	0.25%	0.02%	0.02%	0.52%
TOTAL	183	84	3,686	94	60,266	6,294	39,972	110,579	826,243
	0.17%	0.08%	3.33%	0.09%	54.50%	5.69%	36.15%	100.00%	29.61%
	0.17%	0.08%	3.33%	0.09%	54.50%	5.69%	36.15%	100.00%	29.61%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 7

Number of Protocols with Enrollment Data: **392**

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

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

Legend

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

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

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

Table 8A. Aggregate Enrollment Data for Intramural Research Protocols, Excluding Male-Only and Female-Only Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**920,596**	**299,197**		**32.50%**
%	**35.59%**	**40.28%**		
Males	**1,621,057**	**439,353**		**27.10%**
%	**62.67%**	**59.15%**		
Unknown	**44,806**	**4,270**		**9.53%**
%	**1.73%**	**0.57%**		
TOTAL	**2,586,459**	**742,820**	**28.72%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**1,484**

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

Number of Protocols with Enrollment Data: 1,121

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	9,269	98,376	57,450	551	559,547	78,199	36,090	839,482	692,583	38,835	108,064	839,482
	0.38%	**4.05%**	**2.37%**	**0.02%**	**23.06%**	**3.22%**	**1.49%**	**34.60%**	**28.55%**	**1.60%**	**4.45%**	**34.60%**
	1.10%	*11.72%*	*6.84%*	*0.07%*	*66.65%*	*9.32%*	*4.30%*	*100.00%*	*82.50%*	*4.63%*	*12.87%*	*100.00%*
	45.56%	49.03%	22.52%	42.95%	35.80%	52.12%	15.31%	34.60%	35.31%	44.31%	28.66%	34.60%
Male	11,051	101,911	193,799	732	991,925	71,819	170,604	1,541,841	1,253,067	48,790	239,984	1,541,841
	0.46%	**4.20%**	**7.99%**	**0.03%**	**40.89%**	**2.96%**	7.03%	**63.55%**	**51.65%**	**2.01%**	**9.89%**	**63.55%**
	0.72%	*6.61%*	*12.57%*	*0.05%*	*64.33%*	*4.66%*	11.06%	*100.00%*	*81.27%*	*3.16%*	*15.56%*	*100.00%*
	54.32%	50.79%	75.97%	57.05%	63.46%	47.87%	72.40%	63.55%	63.89%	55.67%	63.64%	63.55%
Unknown	24	369	3,849	0	11,536	19	28,963	44,760	15,715	23	29,022	44,760
	0.00%	**0.02%**	**0.16%**	0.00%	**0.48%**	**0.00%**	*1.19%*	**1.84%**	**0.65%**	**0.00%**	**1.20%**	**1.84%**
	0.05%	*0.82%*	*8.60%*	0.00%	*25.77%*	*0.04%*	*64.71%*	*100.00%*	*35.11%*	*0.05%*	*64.84%*	*100.00%*
	0.12%	0.18%	1.51%	0.00%	0.74%	0.01%	12.29%	1.84%	0.80%	0.03%	7.70%	1.84%
Total	20,344	200,656	255,098	1,283	1,563,008	150,037	235,657	2,426,083	1,961,365	87,648	377,070	2,426,083
	0.84%	**8.27%**	**10.51%**	**0.05%**	**64.43%**	**6.18%**	**9.71%**	**100.00%**	**80.84%**	**3.61%**	**15.54%**	**100.00%**
	0.84%	*8.27%*	*10.51%*	*0.05%*	*64.43%*	*6.18%*	*9.71%*	*100.00%*	*80.84%*	*3.61%*	*15.54%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	69	33	694	28	25,888	3,146	8,977	38,835	278,710
%	**0.08%**	**0.04%**	**0.79%**	**0.03%**	**29.54%**	**3.59%**	**10.24%**	**44.31%**	**11.49%**
	0.18%	*0.08%*	*1.79%*	*0.07%*	*66.66%*	*8.10%*	*23.12%*	*100.00%*	*33.20%*
	51.88%	44.59%	19.42%	44.44%	44.94%	50.61%	44.93%	44.31%	39.53%
Male	63	41	2,880	35	31,721	3,054	10,996	48,790	422,029
%	**0.07%**	**0.05%**	**3.29%**	**0.04%**	**36.19%**	**3.48%**	**12.55%**	**55.67%**	**17.40%**
	0.13%	*0.08%*	*5.90%*	*0.07%*	*65.02%*	*6.26%*	*22.54%*	*100.00%*	*27.37%*
	47.37%	55.41%	80.58%	55.56%	55.06%	49.13%	55.04%	55.67%	59.86%
Unknown	1	0	0	0	0	16	6	23	4,267
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.02%**	**0.01%**	**0.03%**	**0.18%**
	4.35%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*69.57%*	*26.09%*	*100.00%*	*9.53%*
	0.75%	0.00%	0.00%	0.00%	0.00%	0.26%	0.03%	0.03%	0.61%
TOTAL	133	74	3,574	63	57,609	6,216	19,979	87,648	705,006
	0.15%	**0.08%**	**4.08%**	**0.07%**	**65.73%**	**7.09%**	**22.79%**	**100.00%**	**29.06%**
	0.15%	*0.08%*	*4.08%*	*0.07%*	*65.73%*	*7.09%*	*22.79%*	*100.00%*	*29.06%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 8C

Number of Protocols with Enrollment Data:	363

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	134	3,519	12,019	4,815	59,327	1,300	81,114	20,487
	0.08%	**2.19%**	**7.49%**	**3.00%**	**36.99%**	**0.81%**	**50.58%**	**12.77%**
	0.17%	*4.34%*	*14.82%*	*5.94%*	*73.14%*	*1.60%*	*100.00%*	*25.26%*
	47.86%	52.39%	55.20%	53.24%	49.37%	54.58%	50.58%	54.18%
Male	146	3,198	9,752	4,228	60,838	1,054	79,216	17,324
	0.09%	**1.99%**	**6.08%**	**2.64%**	**37.93%**	**0.66%**	**49.39%**	**10.80%**
	0.18%	*4.04%*	*12.31%*	*5.34%*	*76.80%*	*1.33%*	*100.00%*	*21.87%*
	52.14%	47.61%	44.79%	46.75%	50.62%	44.25%	49.39%	45.81%
Unknown	0	0	2	1	15	28	46	3
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.02%**	**0.03%**	**0.00%**
	0.00%	*0.00%*	*4.35%*	*2.17%*	*32.61%*	*60.87%*	*100.00%*	*6.52%*
	0.00%	0.00%	0.01%	0.01%	0.01%	1.18%	0.03%	0.01%
Total	280	6,717	21,773	9,044	120,180	2,382	160,376	37,814
	0.17%	**4.19%**	**13.58%**	**5.64%**	**74.94%**	**1.49%**	**100.00%**	**23.58%**
	0.17%	*4.19%*	*13.58%*	*5.64%*	*74.94%*	*1.49%*	*100.00%*	*23.58%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

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

I. SUMMARY TOTALS: Old Form + New Form

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

Total Number of Protocols with Enrollment Data:	38

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

Number of Protocols with Enrollment Data:	27

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	129	6	594	0	368	2	9,169	10,268	1,282	7,553	1,433	10,268
	0.96%	**0.04%**	**4.42%**	**0.00%**	**2.74%**	**0.01%**	**68.25%**	**76.43%**	**9.54%**	**56.22%**	**10.67%**	**76.43%**
	1.26%	*0.06%*	*5.78%*	*0.00%*	*3.58%*	*0.02%*	*89.30%*	*100.00%*	*12.49%*	*73.56%*	*13.96%*	*100.00%*
	73.30%	24.00%	60.55%	0.00%	58.60%	50.00%	78.91%	76.43%	48.63%	98.27%	46.03%	76.43%
Male	47	19	374	1	260	2	2,451	3,154	1,341	133	1,680	3,154
	0.35%	**0.14%**	**2.78%**	**0.01%**	**1.94%**	**0.01%**	18.24%	**23.48%**	**9.98%**	**0.99%**	**12.50%**	**23.48%**
	1.49%	*0.60%*	*11.86%*	*0.03%*	*8.24%*	*0.06%*	77.71%	*100.00%*	*42.52%*	*4.22%*	*53.27%*	*100.00%*
	26.70%	76.00%	38.12%	100.00%	41.40%	50.00%	21.09%	23.48%	50.87%	1.73%	53.97%	23.48%
Unknown	0	0	13	0	0	0	0	13	13	0	0	13
	0.00%	**0.00%**	**0.10%**	0.00%	**0.00%**	**0.00%**	***0.00%***	**0.10%**	**0.10%**	**0.00%**	**0.00%**	**0.10%**
	0.00%	*0.00%*	*100.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	1.33%	0.00%	0.00%	0.00%	0.00%	0.10%	0.49%	0.00%	0.00%	0.10%
Total	176	25	981	1	628	4	11,620	13,435	2,636	7,686	3,113	13,435
	1.31%	**0.19%**	**7.30%**	**0.01%**	**4.67%**	**0.03%**	**86.49%**	**100.00%**	**19.62%**	**57.21%**	**23.17%**	**100.00%**
	1.31%	*0.19%*	*7.30%*	*0.01%*	4.67%	*0.03%*	*86.49%*	*100.00%*	*19.62%*	*57.21%*	*23.17%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1	0	0	0	2	0	7,550	7,553	8,283
%	**0.01%**	**0.00%**	**0.00%**	**0.00%**	**0.03%**	**0.00%**	**98.23%**	**98.27%**	**61.65%**
	0.01%	*0.00%*	*0.00%*	*0.00%*	*0.03%*	*0.00%*	*99.96%*	*100.00%*	*80.67%*
	100.00%	0.00%	0.00%	0.00%	66.67%	0.00%	98.28%	98.27%	93.36%
Male	0	0	0	0	1	0	132	133	576
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	**1.72%**	**1.73%**	**4.29%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.75%*	*0.00%*	*99.25%*	*100.00%*	*18.26%*
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	1.72%	1.73%	6.49%
Unknown	0	0	0	0	0	0	0	0	13
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.10%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.15%
TOTAL	1	0	0	0	3	0	7,682	7,686	8,872
	0.01%	**0.00%**	**0.00%**	**0.00%**	**0.04%**	**0.00%**	**99.95%**	**100.00%**	**66.04%**
	0.01%	*0.00%*	*0.00%*	*0.00%*	*0.04%*	*0.00%*	*99.95%*	*100.00%*	*66.04%*
	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 9

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

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

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

Legend

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

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

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

Table 10A. Aggregate Enrollment Data for Intramural Phase III Research Protocols, Excluding Male-Only and Female-Only Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	3,848	931		24.19%
%	43.49%	53.11%		
Males	4,988	809		16.22%
%	56.37%	46.15%		
Unknown	13	13		100.00%
%	0.15%	0.74%		
TOTAL	8,849	1,753	19.81%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	33

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

Number of Protocols with Enrollment Data:	23

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	129	6	589	0	368	2	1,703	2,797	1,277	87	1,433	2,797
	2.16%	**0.10%**	**9.88%**	**0.00%**	**6.17%**	**0.03%**	**28.57%**	**46.92%**	**21.42%**	**1.46%**	**24.04%**	**46.92%**
	4.61%	*0.21%*	*21.06%*	*0.00%*	*13.16%*	*0.07%*	*60.89%*	*100.00%*	*45.66%*	*3.11%*	*51.23%*	*100.00%*
	73.30%	24.00%	60.35%	0.00%	58.88%	50.00%	41.00%	46.92%	48.57%	39.55%	46.05%	46.92%
Male	47	19	374	1	257	2	2,451	3,151	1,339	133	1,679	3,151
	0.79%	**0.32%**	**6.27%**	**0.02%**	**4.31%**	**0.03%**	41.12%	**52.86%**	**22.46%**	**2.23%**	**28.17%**	**52.86%**
	1.49%	*0.60%*	*11.87%*	*0.03%*	*8.16%*	*0.06%*	77.78%	*100.00%*	*42.49%*	*4.22%*	*53.28%*	*100.00%*
	26.70%	76.00%	38.32%	100.00%	41.12%	50.00%	59.00%	52.86%	50.93%	60.45%	53.95%	52.86%
Unknown	0	0	13	0	0	0	0	13	13	0	0	13
	0.00%	**0.00%**	**0.22%**	0.00%	**0.00%**	**0.00%**	***0.00%***	**0.22%**	**0.22%**	**0.00%**	**0.00%**	**0.22%**
	0.00%	*0.00%*	*100.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	1.33%	0.00%	0.00%	0.00%	0.00%	0.22%	0.49%	0.00%	0.00%	0.22%
Total	176	25	976	1	625	4	4,154	5,961	2,629	220	3,112	5,961
	2.95%	**0.42%**	**16.37%**	**0.02%**	**10.48%**	**0.07%**	**69.69%**	**100.00%**	**44.10%**	**3.69%**	**52.21%**	**100.00%**
	2.95%	*0.42%*	*16.37%*	*0.02%*	*10.48%*	*0.07%*	69.69%	*100.00%*	*44.10%*	*3.69%*	*52.21%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1	0	0	0	2	0	84	87	812
%	**0.45%**	**0.00%**	**0.00%**	**0.00%**	**0.91%**	**0.00%**	**38.18%**	**39.55%**	**13.62%**
	1.15%	*0.00%*	*0.00%*	*0.00%*	*2.30%*	*0.00%*	*96.55%*	*100.00%*	*29.03%*
	100.00%	0.00%	0.00%	0.00%	66.67%	0.00%	38.89%	39.55%	57.96%
Male	0	0	0	0	1	0	132	133	576
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.45%**	**0.00%**	**60.00%**	**60.45%**	**9.66%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.75%*	*0.00%*	*99.25%*	*100.00%*	*18.28%*
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	61.11%	60.45%	41.11%
Unknown	0	0	0	0	0	0	0	0	13
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.22%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.93%
TOTAL	1	0	0	0	3	0	216	220	1,401
	0.45%	**0.00%**	**0.00%**	**0.00%**	**1.36%**	**0.00%**	**98.18%**	**100.00%**	**23.50%**
	0.45%	*0.00%*	*0.00%*	*0.00%*	*1.36%*	*0.00%*	*98.18%*	*100.00%*	*23.50%*
	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 10C

Number of Protocols with Enrollment Data: **10**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	1	20	69	29	922	10	1,051	119
	0.03%	**0.69%**	**2.39%**	**1.00%**	**31.93%**	**0.35%**	**36.39%**	**4.12%**
	0.10%	*1.90%*	*6.57%*	*2.76%*	*87.73%*	*0.95%*	*100.00%*	*11.32%*
	25.00%	32.79%	32.70%	38.16%	36.70%	41.67%	36.39%	33.81%
Male	3	41	142	47	1,590	14	1,837	233
	0.10%	**1.42%**	**4.92%**	**1.63%**	**55.06%**	**0.48%**	**63.61%**	**8.07%**
	0.16%	*2.23%*	*7.73%*	*2.56%*	*86.55%*	*0.76%*	*100.00%*	*12.68%*
	75.00%	67.21%	67.30%	61.84%	63.30%	58.33%	63.61%	66.19%
Unknown	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	4	61	211	76	2,512	24	2,888	352
	0.14%	**2.11%**	**7.31%**	**2.63%**	**86.98%**	**0.83%**	**100.00%**	**12.19%**
	0.14%	*2.11%*	*7.31%*	*2.63%*	*86.98%*	*0.83%*	*100.00%*	*12.19%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 11A. Domestic Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2008 and Reported in FY2009 Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	**10,748,744**	**2,978,538**		**27.71%**
%	**59.84%**	**59.59%**		
Males	**7,093,702**	**2,003,836**		**28.25%**
%	**39.49%**	**40.09%**		
Unknown	**120,433**	**16,225**		**13.47%**
%	**0.67%**	**0.32%**		
TOTAL	**17,962,879**	**4,998,599**	**27.83%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	**10,269**

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

Number of Protocols with Enrollment Data: 9,540

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	96,805	1,001,009	1,026,323	28,866	7,438,200	175,742	783,288	10,550,233	9,066,598	696,167	787,468	10,550,233
	0.55%	**5.69%**	**5.83%**	**0.16%**	**42.28%**	**1.00%**	**4.45%**	**59.98%**	**51.54%**	**3.96%**	**4.48%**	**59.98%**
	0.92%	*9.49%*	*9.73%*	*0.27%*	*70.50%*	*1.67%*	*7.42%*	*100.00%*	*85.94%*	*6.60%*	*7.46%*	*100.00%*
	66.51%	71.68%	49.66%	60.16%	60.05%	58.08%	62.96%	59.98%	60.08%	60.95%	57.96%	59.98%
Male	48,181	394,403	1,030,750	18,992	4,932,914	125,473	369,659	6,920,372	5,996,690	441,641	482,041	6,920,372
	0.27%	**2.24%**	**5.86%**	**0.11%**	**28.04%**	**0.71%**	2.10%	**39.34%**	**34.09%**	**2.51%**	**2.74%**	**39.34%**
	0.70%	*5.70%*	*14.89%*	*0.27%*	*71.28%*	*1.81%*	5.34%	*100.00%*	*86.65%*	*6.38%*	*6.97%*	*100.00%*
	33.10%	28.24%	49.87%	39.58%	39.82%	41.47%	29.71%	39.34%	39.74%	38.67%	35.48%	39.34%
Unknown	555	997	9,744	123	16,313	1,348	91,176	120,256	26,851	4,363	89,042	120,256
	0.00%	**0.01%**	**0.06%**	0.00%	**0.09%**	**0.01%**	*0.52%*	**0.68%**	**0.15%**	**0.02%**	**0.51%**	**0.68%**
	0.46%	*0.83%*	*8.10%*	0.10%	*13.57%*	*1.12%*	*75.82%*	*100.00%*	*22.33%*	*3.63%*	*74.04%*	*100.00%*
	0.38%	0.07%	0.47%	0.26%	0.13%	0.45%	7.33%	0.68%	0.18%	0.38%	6.55%	0.68%
Total	145,541	1,396,409	2,066,817	47,981	12,387,427	302,563	1,244,123	17,590,861	15,090,139	1,142,171	1,358,551	17,590,861
	0.83%	**7.94%**	**11.75%**	**0.27%**	**70.42%**	**1.72%**	**7.07%**	**100.00%**	**85.78%**	**6.49%**	**7.72%**	**100.00%**
	0.83%	7.94%	11.75%	0.27%	70.42%	1.72%	7.07%	100.00%	85.78%	6.49%	7.72%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	18,927	6,300	25,943	1,757	429,238	29,886	184,134	696,185	2,942,117
%	**1.66%**	**0.55%**	**2.27%**	**0.15%**	**37.57%**	**2.62%**	**16.12%**	**60.94%**	**16.73%**
	2.72%	*0.90%*	*3.73%*	*0.25%*	*61.66%*	*4.29%*	*26.45%*	*100.00%*	*27.89%*
	60.97%	70.79%	31.62%	56.71%	63.04%	59.09%	64.43%	60.94%	59.73%
Male	11,963	2,470	55,549	1303	250,849	20,659	99,014	441,807	1,967,662
%	**1.05%**	**0.22%**	**4.86%**	**0.11%**	**21.96%**	**1.81%**	**8.67%**	**38.68%**	**11.19%**
	2.71%	*0.56%*	*12.57%*	*0.29%*	*56.78%*	*4.68%*	*22.41%*	*100.00%*	*28.43%*
	38.54%	27.76%	67.70%	42.06%	36.84%	40.85%	34.65%	38.68%	39.94%
Unknown	154	129	562	38	811	28	2,641	4,363	16,219
%	**0.01%**	**0.01%**	**0.05%**	**0.00%**	**0.07%**	**0.00%**	**0.23%**	**0.38%**	**0.09%**
	3.53%	*2.96%*	*12.88%*	*0.87%*	*18.59%*	*0.64%*	*60.53%*	*100.00%*	*13.49%*
	0.50%	1.45%	0.68%	1.23%	0.12%	0.06%	0.92%	0.38%	0.33%
TOTAL	31,044	8,899	82,054	3,098	680,898	50,573	285,789	1,142,355	4,925,998
	2.72%	**0.78%**	**7.18%**	**0.27%**	**59.60%**	**4.43%**	**25.02%**	**100.00%**	**28.00%**
	2.72%	*0.78%*	*7.18%*	*0.27%*	*59.60%*	*4.43%*	*25.02%*	*100.00%*	*28.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 11C

Number of Protocols with Enrollment Data: **729**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	688	6,140	20,989	8,604	154,362	7,728	198,511	36,421
	0.18%	**1.65%**	**5.64%**	**2.31%**	**41.49%**	**2.08%**	**53.36%**	**9.79%**
	0.35%	*3.09%*	*10.57%*	*4.33%*	*77.76%*	*3.89%*	*100.00%*	*18.35%*
	59.06%	54.80%	49.72%	47.75%	54.22%	52.57%	53.36%	50.17%
Male	477	5,063	21,221	9,413	130,327	6,829	173,330	36,174
	0.13%	**1.36%**	**5.70%**	**2.53%**	**35.03%**	**1.84%**	**46.59%**	**9.72%**
	0.28%	*2.92%*	*12.24%*	*5.43%*	*75.19%*	*3.94%*	*100.00%*	*20.87%*
	40.94%	45.19%	50.27%	52.24%	45.77%	46.46%	46.59%	49.83%
Unknown	0	1	3	2	28	143	177	6
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.04%**	**0.05%**	**0.00%**
	0.00%	*0.56%*	*1.69%*	*1.13%*	*15.82%*	*80.79%*	*100.00%*	*3.39%*
	0.00%	0.01%	0.01%	0.01%	0.01%	0.97%	0.05%	0.01%
Total	1,165	11,204	42,213	18,019	284,717	14,700	372,018	72,601
	0.31%	**3.01%**	**11.35%**	**4.84%**	**76.53%**	**3.95%**	**100.00%**	**19.52%**
	0.31%	*3.01%*	*11.35%*	*4.84%*	*76.53%*	*3.95%*	*100.00%*	*19.52%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 12A. Domestic Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	9,842,191	2,751,770		27.96%
%	63.31%	62.27%		
Males	5,624,890	1,655,241		29.43%
%	36.18%	37.45%		
Unknown	79,269	12,303		15.52%
%	0.51%	0.28%		
TOTAL	15,546,350	4,419,314	28.43%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	8,637

Number of Protocols with Enrollment Data: 8,300

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	86,990	982,569	959,822	28,214	6,849,203	100,892	718,026	9,725,716	8,407,291	659,165	659,260	9,725,716
	0.57%	**6.41%**	**6.26%**	**0.18%**	**44.66%**	**0.66%**	**4.68%**	**63.42%**	**54.82%**	**4.30%**	**4.30%**	**63.42%**
	0.89%	*10.10%*	*9.87%*	*0.29%*	*70.42%*	*1.04%*	*7.38%*	*100.00%*	*86.44%*	*6.78%*	*6.78%*	*100.00%*
	69.79%	72.26%	53.14%	60.55%	63.10%	64.09%	72.75%	63.42%	63.18%	62.12%	68.10%	63.42%
Male	37,117	376,314	840,596	18,260	3,997,547	55,193	205,928	5,530,955	4,885,375	397,572	248,008	5,530,955
	0.24%	**2.45%**	**5.48%**	**0.12%**	**26.07%**	**0.36%**	1.34%	**36.07%**	**31.86%**	**2.59%**	**1.62%**	**36.07%**
	0.67%	*6.80%*	*15.20%*	*0.33%*	*72.28%*	*1.00%*	3.72%	*100.00%*	*88.33%*	*7.19%*	*4.48%*	*100.00%*
	29.78%	27.67%	46.54%	39.19%	36.83%	35.06%	20.86%	36.07%	36.71%	37.47%	25.62%	36.07%
Unknown	531	960	5,895	123	7,262	1,345	63,022	79,138	13,953	4,356	60,829	79,138
	0.00%	**0.01%**	**0.04%**	0.00%	**0.05%**	**0.01%**	***0.41%***	**0.52%**	**0.09%**	**0.03%**	**0.40%**	**0.52%**
	0.67%	*1.21%*	*7.45%*	0.16%	*9.18%*	*1.70%*	*79.64%*	*100.00%*	*17.63%*	*5.50%*	*76.86%*	*100.00%*
	0.43%	0.07%	0.33%	0.26%	0.07%	0.85%	6.39%	0.52%	0.10%	0.41%	6.28%	0.52%
Total	124,638	1,359,843	1,806,313	46,597	10,854,012	157,430	986,976	15,335,809	13,306,619	1,061,093	968,097	15,335,809
	0.81%	**8.87%**	**11.78%**	**0.30%**	**70.78%**	**1.03%**	**6.44%**	**100.00%**	**86.77%**	**6.92%**	**6.31%**	**100.00%**
	0.81%	*8.87%*	*11.78%*	*0.30%*	*70.78%*	*1.03%*	*6.44%*	*100.00%*	*86.77%*	*6.92%*	*6.31%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	18,813	6,257	25,250	1,699	401,450	29,591	176,123	659,183	2,736,060
%	**1.77%**	**0.59%**	**2.38%**	**0.16%**	**37.83%**	**2.79%**	**16.60%**	**62.11%**	**17.84%**
	2.85%	*0.95%*	*3.83%*	*0.26%*	*60.90%*	*4.49%*	*26.72%*	*100.00%*	*28.13%*
	60.95%	70.98%	32.15%	56.54%	64.56%	59.07%	65.68%	62.11%	62.40%
Male	11,899	2,429	52,724	1268	219,538	20,478	89,402	397,738	1,636,420
%	**1.12%**	**0.23%**	**4.97%**	**0.12%**	**20.69%**	**1.93%**	**8.42%**	**37.48%**	**10.67%**
	2.99%	*0.61%*	*13.26%*	*0.32%*	*55.20%*	*5.15%*	*22.48%*	*100.00%*	*29.59%*
	38.55%	27.56%	67.13%	42.20%	35.31%	40.88%	33.34%	37.48%	37.32%
Unknown	153	129	562	38	811	28	2,635	4,356	12,300
%	**0.01%**	**0.01%**	**0.05%**	**0.00%**	**0.08%**	**0.00%**	**0.25%**	**0.41%**	**0.08%**
	3.51%	*2.96%*	*12.90%*	*0.87%*	*18.62%*	*0.64%*	*60.49%*	*100.00%*	*15.54%*
	0.50%	1.46%	0.72%	1.26%	0.13%	0.06%	0.98%	0.41%	0.28%
TOTAL	30,865	8,815	78,536	3,005	621,799	50,097	268,160	1,061,277	4,384,780
	2.91%	**0.83%**	**7.40%**	**0.28%**	**58.59%**	**4.72%**	**25.27%**	**100.00%**	**28.59%**
	2.91%	*0.83%*	*7.40%*	*0.28%*	*58.59%*	*4.72%*	*25.27%*	*100.00%*	*28.59%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 12C

Number of Protocols with Enrollment Data: **337**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	553	2,592	8,810	3,755	94,353	6,412	116,475	15,710
	0.26%	**1.23%**	**4.18%**	**1.78%**	**44.81%**	**3.05%**	**55.32%**	**7.46%**
	0.47%	*2.23%*	*7.56%*	*3.22%*	*81.01%*	*5.51%*	*100.00%*	*13.49%*
	62.56%	58.17%	43.49%	42.02%	57.64%	52.13%	55.32%	45.49%
Male	331	1,863	11,446	5,181	69,340	5,774	93,935	18,821
	0.16%	**0.88%**	**5.44%**	**2.46%**	**32.93%**	**2.74%**	**44.62%**	**8.94%**
	0.35%	*1.98%*	*12.19%*	*5.52%*	*73.82%*	*6.15%*	*100.00%*	*20.04%*
	37.44%	41.81%	56.50%	57.97%	42.36%	46.94%	44.62%	54.50%
Unknown	0	1	1	1	13	115	131	3
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.05%**	**0.06%**	**0.00%**
	0.00%	*0.76%*	*0.76%*	*0.76%*	*9.92%*	*87.79%*	*100.00%*	*2.29%*
	0.00%	0.02%	0.00%	0.01%	0.01%	0.93%	0.06%	0.01%
Total	884	4,456	20,257	8,937	163,706	12,301	210,541	34,534
	0.42%	**2.12%**	**9.62%**	**4.24%**	**77.75%**	**5.84%**	**100.00%**	**16.40%**
	0.42%	*2.12%*	*9.62%*	*4.24%*	*77.75%*	*5.84%*	*100.00%*	*16.40%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 13A. Domestic Aggregate Enrollment Data for Intramural Research Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	906,553	226,768		25.01%
%	37.51%	39.15%		
Males	1,468,812	348,595		23.73%
%	60.78%	60.18%		
Unknown	41,164	3,922		9.53%
%	1.70%	0.68%		
TOTAL	2,416,529	579,285	23.97%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	1,632

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

Number of Protocols with Enrollment Data: 1,240

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	9,815	18,440	66,501	652	588,997	74,850	65,262	824,517	659,307	37,002	128,208	824,517
	0.44%	**0.82%**	**2.95%**	**0.03%**	**26.12%**	**3.32%**	**2.89%**	**36.56%**	**29.24%**	**1.64%**	**5.69%**	**36.56%**
	1.19%	*2.24%*	*8.07%*	*0.08%*	*71.44%*	*9.08%*	*7.92%*	*100.00%*	*79.96%*	*4.49%*	*15.55%*	*100.00%*
	46.95%	50.43%	25.53%	47.11%	38.41%	51.57%	25.38%	36.56%	36.97%	45.64%	32.84%	36.56%
Male	11,064	18,089	190,154	732	935,367	70,280	163,731	1,389,417	1,111,315	44,069	234,033	1,389,417
	0.49%	**0.80%**	**8.43%**	**0.03%**	**41.48%**	**3.12%**	7.26%	**61.61%**	**49.28%**	**1.95%**	**10.38%**	**61.61%**
	0.80%	*1.30%*	*13.69%*	*0.05%*	*67.32%*	*5.06%*	11.78%	*100.00%*	*79.98%*	*3.17%*	*16.84%*	*100.00%*
	52.93%	49.47%	72.99%	52.89%	61.00%	48.42%	63.67%	61.61%	62.31%	54.35%	59.94%	61.61%
Unknown	24	37	3,849	0	9,051	3	28,154	41,118	12,898	7	28,213	41,118
	0.00%	**0.00%**	**0.17%**	0.00%	**0.40%**	**0.00%**	*1.25%*	**1.82%**	**0.57%**	**0.00%**	**1.25%**	**1.82%**
	0.06%	*0.09%*	*9.36%*	0.00%	*22.01%*	*0.01%*	*68.47%*	*100.00%*	*31.37%*	*0.02%*	*68.61%*	*100.00%*
	0.11%	0.10%	1.48%	0.00%	0.59%	0.00%	10.95%	1.82%	0.72%	0.01%	7.23%	1.82%
Total	20,903	36,566	260,504	1,384	1,533,415	145,133	257,147	2,255,052	1,783,520	81,078	390,454	2,255,052
	0.93%	**1.62%**	**11.55%**	**0.06%**	**68.00%**	**6.44%**	**11.40%**	**100.00%**	**79.09%**	**3.60%**	**17.31%**	**100.00%**
	0.93%	*1.62%*	*11.55%*	*0.06%*	*68.00%*	*6.44%*	*11.40%*	*100.00%*	*79.09%*	*3.60%*	*17.31%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female %	114	43	693	58	27,788	295	8,011	37,002	206,057
	0.14%	**0.05%**	**0.85%**	**0.07%**	**34.27%**	**0.36%**	**9.88%**	**45.64%**	**9.14%**
	0.31%	*0.12%*	*1.87%*	*0.16%*	*75.10%*	*0.80%*	*21.65%*	*100.00%*	*24.99%*
	63.69%	51.19%	19.70%	62.37%	47.02%	61.97%	45.44%	45.64%	38.07%
Male %	64	41	2,825	35	31,311	181	9,612	44,069	331,242
	0.08%	**0.05%**	**3.48%**	**0.04%**	**38.62%**	**0.22%**	**11.86%**	**54.35%**	**14.69%**
	0.15%	*0.09%*	*6.41%*	*0.08%*	*71.05%*	*0.41%*	*21.81%*	*100.00%*	*23.84%*
	35.75%	48.81%	80.30%	37.63%	52.98%	38.03%	54.52%	54.35%	61.20%
Unknown %	1	0	0	0	0	0	6	7	3,919
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.01%**	**0.17%**
	14.29%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*85.71%*	*100.00%*	*9.53%*
	0.56%	0.00%	0.00%	0.00%	0.00%	0.00%	0.03%	0.01%	0.72%
TOTAL	179	84	3,518	93	59,099	476	17,629	81,078	541,218
	0.22%	**0.10%**	**4.34%**	**0.11%**	**72.89%**	**0.59%**	**21.74%**	**100.00%**	**24.00%**
	0.22%	*0.10%*	*4.34%*	*0.11%*	*72.89%*	*0.59%*	*21.74%*	*100.00%*	*24.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 13C

Number of Protocols with Enrollment Data: **392**

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

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

Legend

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

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

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

Table 14A. Domestic Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	285,066	112,002		39.29%
%	52.53%	53.25%		
Males	227,575	97,625		42.90%
%	41.93%	46.42%		
Unknown	30,059	690		2.30%
%	5.54%	0.33%		
TOTAL	542,700	210,317	38.75%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	423

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

Number of Protocols with Enrollment Data: 310

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	9,726	42,237	30,320	431	102,348	2,277	14,091	201,430	169,086	26,428	5,916	201,430
	2.46%	10.68%	7.67%	0.11%	25.89%	0.58%	3.56%	50.96%	42.77%	6.69%	1.50%	50.96%
	4.83%	20.97%	15.05%	0.21%	50.81%	1.13%	7.00%	100.00%	83.94%	13.12%	2.94%	100.00%
	56.22%	50.80%	56.20%	51.13%	56.02%	48.78%	26.74%	50.96%	54.10%	59.98%	15.28%	50.96%
Male	7,516	40,810	23,466	408	79,315	2,332	9,995	163,842	142,134	17,255	4,453	163,842
	1.90%	10.32%	5.94%	0.10%	20.06%	0.59%	2.53%	41.45%	35.96%	4.37%	1.13%	41.45%
	4.59%	24.91%	14.32%	0.25%	48.41%	1.42%	6.10%	100.00%	86.75%	10.53%	2.72%	100.00%
	43.45%	49.08%	43.49%	48.40%	43.41%	49.96%	18.97%	41.45%	45.48%	39.16%	11.50%	41.45%
Unknown	57	101	166	4	1,029	59	28,613	30,029	1,305	379	28,345	30,029
	0.01%	0.03%	0.04%	0.00%	0.26%	0.01%	7.24%	7.60%	0.33%	0.10%	7.17%	7.60%
	0.19%	0.34%	0.55%	0.01%	3.43%	0.20%	95.28%	100.00%	4.35%	1.26%	94.39%	100.00%
	0.33%	0.12%	0.31%	0.47%	0.56%	1.26%	54.30%	7.60%	0.42%	0.86%	73.22%	7.60%
Total	17,299	83,148	53,952	843	182,692	4,668	52,699	395,301	312,525	44,062	38,714	395,301
	4.38%	21.03%	13.65%	0.21%	46.22%	1.18%	13.33%	100.00%	79.06%	11.15%	9.79%	100.00%
	4.38%	21.03%	13.65%	0.21%	46.22%	1.18%	13.33%	100.00%	79.06%	11.15%	9.79%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	8,727	137	485	98	6,954	431	9,596	26,428	101,541
%	19.81%	0.31%	1.10%	0.22%	15.78%	0.98%	21.78%	59.98%	25.69%
	33.02%	0.52%	1.84%	0.37%	26.31%	1.63%	36.31%	100.00%	50.41%
	57.00%	39.14%	52.15%	49.75%	62.69%	44.71%	63.06%	59.98%	54.53%
Male	6,543	203	435	95	4,077	521	5,381	17,255	83,990
%	14.85%	0.46%	0.99%	0.22%	9.25%	1.18%	12.21%	39.16%	21.25%
	37.92%	1.18%	2.52%	0.55%	23.63%	3.02%	31.19%	100.00%	51.26%
	42.73%	58.00%	46.77%	48.22%	36.75%	54.05%	35.36%	39.16%	45.10%
Unknown	41	10	10	4	62	12	240	379	689
%	0.09%	0.02%	0.02%	0.01%	0.14%	0.03%	0.54%	0.86%	0.17%
	10.82%	2.64%	2.64%	1.06%	16.36%	3.17%	63.32%	100.00%	2.29%
	0.27%	2.86%	1.08%	2.03%	0.56%	1.24%	1.58%	0.86%	0.37%
TOTAL	15,311	350	930	197	11,093	964	15,217	44,062	186,220
	34.75%	0.79%	2.11%	0.45%	25.18%	2.19%	34.54%	100.00%	47.11%
	34.75%	0.79%	2.11%	0.45%	25.18%	2.19%	34.54%	100.00%	47.11%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 14C

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

Number of Protocols with Enrollment Data: **113**

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	321	1,788	5,941	2,411	71,565	1,610	83,636	10,461
	0.22%	**1.21%**	**4.03%**	**1.64%**	**48.55%**	**1.09%**	**56.74%**	**7.10%**
	0.38%	*2.14%*	*7.10%*	*2.88%*	*85.57%*	*1.93%*	*100.00%*	*12.51%*
	56.81%	63.88%	40.85%	38.94%	59.60%	49.78%	56.74%	43.41%
Male	244	1,011	8,600	3,780	48,494	1,604	63,733	13,635
	0.17%	**0.69%**	**5.83%**	**2.56%**	**32.90%**	**1.09%**	**43.24%**	**9.25%**
	0.38%	*1.59%*	*13.49%*	*5.93%*	*76.09%*	*2.52%*	*100.00%*	*21.39%*
	43.19%	36.12%	59.14%	61.06%	40.39%	49.60%	43.24%	56.58%
Unknown	0	0	1	0	9	20	30	1
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.01%**	**0.02%**	**0.00%**
	0.00%	*0.00%*	*3.33%*	*0.00%*	*30.00%*	*66.67%*	*100.00%*	*3.33%*
	0.00%	0.00%	0.01%	0.00%	0.01%	0.62%	0.02%	0.00%
Total	565	2,799	14,542	6,191	120,068	3,234	147,399	24,097
	0.38%	**1.90%**	**9.87%**	**4.20%**	**81.46%**	**2.19%**	**100.00%**	**16.35%**
	0.38%	*1.90%*	*9.87%*	*4.20%*	*81.46%*	*2.19%*	*100.00%*	*16.35%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 15A. Domestic Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	**Total Enrollment**	**Minority Enrollment**	**Total % Minority**	**% Minority by Sex**
Females	**2,389**	**818**		**34.24%**
%	**39.82%**	**52.20%**		
Males	**3,598**	**736**		**20.46%**
%	**59.97%**	**46.97%**		
Unknown	**13**	**13**		**100.00%**
%	**0.22%**	**0.83%**		
TOTAL	**6,000**	**1,567**	**26.12%**	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: **34**

Number of Protocols with Enrollment Data: **23**

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

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	129	6	502	0	368	2	331	1,338	1,190	61	87	1,338
	4.36%	**0.20%**	**16.96%**	**0.00%**	**12.43%**	**0.07%**	**11.18%**	**45.20%**	**40.20%**	**2.06%**	**2.94%**	**45.20%**
	9.64%	*0.45%*	*37.52%*	*0.00%*	*27.50%*	*0.15%*	*24.74%*	*100.00%*	*88.94%*	*4.56%*	*6.50%*	*100.00%*
	73.30%	24.00%	60.77%	0.00%	58.60%	50.00%	25.46%	45.20%	47.96%	36.97%	27.71%	45.20%
Male	47	19	311	1	260	2	969	1,609	1,278	104	227	1,609
	1.59%	**0.64%**	**10.51%**	**0.03%**	**8.78%**	**0.07%**	32.74%	**54.36%**	**43.18%**	**3.51%**	**7.67%**	**54.36%**
	2.92%	*1.18%*	*19.33%*	*0.06%*	*16.16%*	*0.12%*	60.22%	*100.00%*	*79.43%*	*6.46%*	*14.11%*	*100.00%*
	26.70%	76.00%	37.65%	100.00%	41.40%	50.00%	74.54%	54.36%	51.51%	63.03%	72.29%	54.36%
Unknown	0	0	13	0	0	0	0	13	13	0	0	13
	0.00%	**0.00%**	**0.44%**	0.00%	**0.00%**	**0.00%**	***0.00%***	**0.44%**	**0.44%**	**0.00%**	**0.00%**	**0.44%**
	0.00%	*0.00%*	*100.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	1.57%	0.00%	0.00%	0.00%	0.00%	0.44%	0.52%	0.00%	0.00%	0.44%
Total	176	25	826	1	628	4	1,300	2,960	2,481	165	314	2,960
	5.95%	**0.84%**	**27.91%**	**0.03%**	**21.22%**	**0.14%**	**43.92%**	**100.00%**	**83.82%**	**5.57%**	**10.61%**	**100.00%**
	5.95%	*0.84%*	*27.91%*	*0.03%*	*21.22%*	*0.14%*	*43.92%*	*100.00%*	*83.82%*	*5.57%*	*10.61%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown/ Other**	**Total**	**Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**
Female	1	0	0	0	2	0	58	61	699
%	**0.61%**	**0.00%**	**0.00%**	**0.00%**	**1.21%**	**0.00%**	**35.15%**	**36.97%**	**23.61%**
	1.64%	*0.00%*	*0.00%*	*0.00%*	*3.28%*	*0.00%*	*95.08%*	*100.00%*	*52.24%*
	100.00%	0.00%	0.00%	0.00%	66.67%	0.00%	36.02%	36.97%	58.44%
Male	0	0	0	0	1	0	103	104	484
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.61%**	**0.00%**	**62.42%**	**63.03%**	**16.35%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.96%*	*0.00%*	*99.04%*	*100.00%*	*30.08%*
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	63.98%	63.03%	40.47%
Unknown	0	0	0	0	0	0	0	0	13
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.44%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	1.09%
TOTAL	1	0	0	0	3	0	161	165	1,196
	0.61%	**0.00%**	**0.00%**	**0.00%**	**1.82%**	**0.00%**	**97.58%**	**100.00%**	**40.41%**
	0.61%	*0.00%*	*0.00%*	*0.00%*	*1.82%*	*0.00%*	*97.58%*	*100.00%*	*40.41%*
	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 15C

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

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

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

Legend

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

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

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

Table 16A. Foreign Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	690,399	460,454		66.69%
%	58.71%	58.66%		
Males	476,944	321,566		67.42%
%	40.56%	40.97%		
Unknown	8,516	2,924		34.34%
%	0.72%	0.37%		
TOTAL	1,175,859	784,944	66.75%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	902

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

Number of Protocols with Enrollment Data: 788

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	4,658	265,687	119,867	1,169	241,262	11,509	36,457	680,609	559,043	93,773	27,793	680,609
	0.40%	**22.94%**	**10.35%**	**0.10%**	**20.83%**	**0.99%**	**3.15%**	**58.75%**	**48.26%**	**8.09%**	**2.40%**	**58.75%**
	0.68%	*39.04%*	*17.61%*	*0.17%*	*35.45%*	*1.69%*	*5.36%*	*100.00%*	*82.14%*	*13.78%*	*4.08%*	*100.00%*
	51.91%	59.82%	54.30%	49.58%	59.79%	54.09%	63.52%	58.75%	59.26%	58.33%	51.25%	58.75%
Male	4,294	177,684	98,990	1,189	159,202	9,738	18,200	469,297	379,832	66,744	22,721	469,297
	0.37%	**15.34%**	**8.55%**	**0.10%**	**13.74%**	**0.84%**	1.57%	**40.51%**	**32.79%**	**5.76%**	**1.96%**	**40.51%**
	0.91%	*37.86%*	*21.09%*	*0.25%*	*33.92%*	*2.08%*	3.88%	*100.00%*	*80.94%*	*14.22%*	*4.84%*	*100.00%*
	47.85%	40.01%	44.84%	50.42%	39.45%	45.77%	31.71%	40.51%	40.26%	41.51%	41.90%	40.51%
Unknown	22	759	1,903	0	3,054	29	2,738	8,505	4,533	256	3,716	8,505
	0.00%	**0.07%**	**0.16%**	0.00%	**0.26%**	**0.00%**	***0.24%***	**0.73%**	**0.39%**	**0.02%**	**0.32%**	**0.73%**
	0.26%	*8.92%*	*22.38%*	0.00%	*35.91%*	*0.34%*	*32.19%*	*100.00%*	*53.30%*	*3.01%*	*43.69%*	*100.00%*
	0.25%	0.17%	0.86%	0.00%	0.76%	0.14%	4.77%	0.73%	0.48%	0.16%	6.85%	0.73%
Total	8,974	444,130	220,760	2,358	403,518	21,276	57,395	1,158,411	943,408	160,773	54,230	1,158,411
	0.77%	**38.34%**	**19.06%**	**0.20%**	**34.83%**	**1.84%**	**4.95%**	**100.00%**	**81.44%**	**13.88%**	**4.68%**	**100.00%**
	0.77%	*38.34%*	*19.06%*	*0.20%*	*34.83%*	*1.84%*	4.95%	*100.00%*	*81.44%*	*13.88%*	*4.68%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	4,052	22,730	4,401	3	27,060	6,711	28,816	93,773	458,766
%	**2.52%**	**14.14%**	**2.74%**	**0.00%**	**16.83%**	**4.17%**	**17.92%**	**58.33%**	**39.60%**
	4.32%	*24.24%*	*4.69%*	*0.00%*	*28.86%*	*7.16%*	*30.73%*	*100.00%*	*67.41%*
	49.69%	50.91%	48.20%	60.00%	55.84%	50.23%	77.84%	58.33%	58.59%
Male	4,087	21,917	4,725	2	21,388	6,623	8,002	66,744	321,285
%	**2.54%**	**13.63%**	**2.94%**	**0.00%**	**13.30%**	**4.12%**	**4.98%**	**41.51%**	**27.73%**
	6.12%	*32.84%*	*7.08%*	*0.00%*	*32.04%*	*9.92%*	*11.99%*	*100.00%*	*68.46%*
	50.12%	49.09%	51.75%	40.00%	44.14%	49.57%	21.62%	41.51%	41.03%
Unknown	15	0	4	0	9	27	201	256	2,923
%	**0.01%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.02%**	**0.13%**	**0.16%**	**0.25%**
	5.86%	*0.00%*	*1.56%*	*0.00%*	*3.52%*	*10.55%*	*78.52%*	*100.00%*	*34.37%*
	0.18%	0.00%	0.04%	0.00%	0.02%	0.20%	0.54%	0.16%	0.37%
TOTAL	8,154	44,647	9,130	5	48,457	13,361	37,019	160,773	782,974
	5.07%	**27.77%**	**5.68%**	**0.00%**	**30.14%**	**8.31%**	**23.03%**	**100.00%**	**67.59%**
	5.07%	*27.77%*	*5.68%*	*0.00%*	*30.14%*	*8.31%*	*23.03%*	*100.00%*	*67.59%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 16C

Number of Protocols with Enrollment Data: **114**

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	32	316	116	1,224	7,830	272	9,790	1,688
	0.18%	**1.81%**	**0.66%**	**7.02%**	**44.88%**	**1.56%**	**56.11%**	**9.67%**
	0.33%	*3.23%*	*1.18%*	*12.50%*	*79.98%*	*2.78%*	*100.00%*	*17.24%*
	66.67%	70.54%	60.42%	95.48%	54.38%	25.19%	56.11%	85.69%
Male	16	131	76	58	6,566	800	7,647	281
	0.09%	**0.75%**	**0.44%**	**0.33%**	**37.63%**	**4.59%**	**43.83%**	**1.61%**
	0.21%	*1.71%*	*0.99%*	*0.76%*	*85.86%*	*10.46%*	*100.00%*	*3.67%*
	33.33%	29.24%	39.58%	4.52%	45.60%	74.07%	43.83%	14.26%
Unknown	0	1	0	0	2	8	11	1
	0.00%	**0.01%**	**0.00%**	**0.00%**	**0.01%**	**0.05%**	**0.06%**	**0.01%**
	0.00%	*9.09%*	*0.00%*	*0.00%*	*18.18%*	*72.73%*	*100.00%*	*9.09%*
	0.00%	0.22%	0.00%	0.00%	0.01%	0.74%	0.06%	0.05%
Total	48	448	192	1,282	14,398	1,080	17,448	1,970
	0.28%	**2.57%**	**1.10%**	**7.35%**	**82.52%**	**6.19%**	**100.00%**	**11.29%**
	0.28%	*2.57%*	*1.10%*	*7.35%*	*82.52%*	*6.19%*	*100.00%*	*11.29%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 17A. Foreign Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	346,055	271,168		78.36%
%	54.01%	54.24%		
Males	289,786	226,175		78.05%
%	45.23%	45.24%		
Unknown	4,874	2,576		52.85%
%	0.76%	0.52%		
TOTAL	640,715	499,919	78.03%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	807

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

Number of Protocols with Enrollment Data: 693

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	4,653	107,986	113,868	1,167	90,258	7,507	10,826	336,265	250,847	69,149	16,269	336,265
	0.75%	17.33%	18.27%	0.19%	14.48%	1.20%	1.74%	53.95%	40.25%	11.09%	2.61%	53.95%
	1.38%	32.11%	33.86%	0.35%	26.84%	2.23%	3.22%	100.00%	74.60%	20.56%	4.84%	100.00%
	51.88%	53.44%	54.47%	50.76%	54.61%	55.13%	49.21%	53.95%	54.51%	52.68%	51.21%	53.95%
Male	4,294	93,642	93,271	1,132	74,458	6,098	9,244	282,139	207,663	61,883	12,593	282,139
	0.69%	15.02%	14.96%	0.18%	11.95%	0.98%	1.48%	45.27%	33.32%	9.93%	2.02%	45.27%
	1.52%	33.19%	33.06%	0.40%	26.39%	2.16%	3.28%	100.00%	73.60%	21.93%	4.46%	100.00%
	47.88%	46.34%	44.62%	49.24%	45.05%	44.78%	42.02%	45.27%	45.12%	47.14%	39.64%	45.27%
Unknown	22	427	1,903	0	569	13	1,929	4,863	1,716	240	2,907	4,863
	0.00%	0.07%	0.31%	0.00%	0.09%	0.00%	0.31%	0.78%	0.28%	0.04%	0.47%	0.78%
	0.45%	8.78%	39.13%	0.00%	11.70%	0.27%	39.67%	100.00%	35.29%	4.94%	59.78%	100.00%
	0.25%	0.21%	0.91%	0.00%	0.34%	0.10%	8.77%	0.78%	0.37%	0.18%	9.15%	0.78%
Total	8,969	202,055	209,042	2,299	165,285	13,618	21,999	623,267	460,226	131,272	31,769	623,267
	1.44%	32.42%	33.54%	0.37%	26.52%	2.18%	3.53%	100.00%	73.84%	21.06%	5.10%	100.00%
	1.44%	32.42%	33.54%	0.37%	26.52%	2.18%	3.53%	100.00%	73.84%	21.06%	5.10%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female %	4,048	22,730	4,288	2	26,324	3,782	7,975	69,149	269,480
	3.08%	17.32%	3.27%	0.00%	20.05%	2.88%	6.08%	52.68%	43.24%
	5.85%	32.87%	6.20%	0.00%	38.07%	5.47%	11.53%	100.00%	80.14%
	49.67%	50.91%	47.85%	50.00%	55.67%	50.14%	54.34%	52.68%	54.12%
Male %	4,087	21,917	4,670	2	20,957	3,750	6,500	61,883	225,894
	3.11%	16.70%	3.56%	0.00%	15.96%	2.86%	4.95%	47.14%	36.24%
	6.60%	35.42%	7.55%	0.00%	33.87%	6.06%	10.50%	100.00%	80.06%
	50.15%	49.09%	52.11%	50.00%	44.32%	49.71%	44.29%	47.14%	45.36%
Unknown %	15	0	4	0	9	11	201	240	2,575
	0.01%	0.00%	0.00%	0.00%	0.01%	0.01%	0.15%	0.18%	0.41%
	6.25%	0.00%	1.67%	0.00%	3.75%	4.58%	83.75%	100.00%	52.95%
	0.18%	0.00%	0.04%	0.00%	0.02%	0.15%	1.37%	0.18%	0.52%
TOTAL	8,150	44,647	8,962	4	47,290	7,543	14,676	131,272	497,949
	6.21%	34.01%	6.83%	0.00%	36.02%	5.75%	11.18%	100.00%	79.89%
	6.21%	34.01%	6.83%	0.00%	36.02%	5.75%	11.18%	100.00%	79.89%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 17C

Number of Protocols with Enrollment Data: **114**

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

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	32	316	116	1,224	7,830	272	9,790	1,688
	0.18%	**1.81%**	**0.66%**	**7.02%**	**44.88%**	**1.56%**	**56.11%**	**9.67%**
	0.33%	*3.23%*	*1.18%*	*12.50%*	*79.98%*	*2.78%*	*100.00%*	*17.24%*
	66.67%	70.54%	60.42%	95.48%	54.38%	25.19%	56.11%	85.69%
Male	16	131	76	58	6,566	800	7,647	281
	0.09%	**0.75%**	**0.44%**	**0.33%**	**37.63%**	**4.59%**	**43.83%**	**1.61%**
	0.21%	*1.71%*	*0.99%*	*0.76%*	*85.86%*	*10.46%*	*100.00%*	*3.67%*
	33.33%	29.24%	39.58%	4.52%	45.60%	74.07%	43.83%	14.26%
Unknown	0	1	0	0	2	8	11	1
	0.00%	**0.01%**	**0.00%**	**0.00%**	**0.01%**	**0.05%**	**0.06%**	**0.01%**
	0.00%	*9.09%*	*0.00%*	*0.00%*	*18.18%*	*72.73%*	*100.00%*	*9.09%*
	0.00%	0.22%	0.00%	0.00%	0.01%	0.74%	0.06%	0.05%
Total	48	448	192	1,282	14,398	1,080	17,448	1,970
	0.28%	**2.57%**	**1.10%**	**7.35%**	**82.52%**	**6.19%**	**100.00%**	**11.29%**
	0.28%	*2.57%*	*1.10%*	*7.35%*	*82.52%*	*6.19%*	*100.00%*	*11.29%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

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

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	344,344	189,286		54.97%
%	64.35%	66.41%		
Males	187,158	95,391		50.97%
%	34.97%	33.47%		
Unknown	3,642	348		9.56%
%	0.68%	0.12%		
TOTAL	535,144	285,025	53.26%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	95

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

Number of Protocols with Enrollment Data: 95

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	5	157,701	5,999	2	151,004	4,002	25,631	344,344	308,196	24,624	11,524	344,344
	0.00%	**29.47%**	**1.12%**	**0.00%**	**28.22%**	**0.75%**	**4.79%**	**64.35%**	**57.59%**	**4.60%**	**2.15%**	**64.35%**
	0.00%	*45.80%*	*1.74%*	*0.00%*	*43.85%*	*1.16%*	*7.44%*	*100.00%*	*89.50%*	*7.15%*	*3.35%*	*100.00%*
	100.00%	65.15%	51.19%	3.39%	63.39%	52.26%	72.41%	64.35%	63.78%	83.47%	51.31%	64.35%
Male	0	84,042	5,719	57	84,744	3,640	8,956	187,158	172,169	4,861	10,128	187,158
	0.00%	**15.70%**	**1.07%**	**0.01%**	**15.84%**	**0.68%**	1.67%	**34.97%**	**32.17%**	**0.91%**	**1.89%**	**34.97%**
	0.00%	*44.90%*	*3.06%*	*0.03%*	*45.28%*	*1.94%*	4.79%	*100.00%*	*91.99%*	*2.60%*	*5.41%*	*100.00%*
	0.00%	34.72%	48.81%	96.61%	35.57%	47.53%	25.30%	34.97%	35.63%	16.48%	45.09%	34.97%
Unknown	0	332	0	0	2,485	16	809	3,642	2,817	16	809	3,642
	0.00%	**0.06%**	**0.00%**	0.00%	**0.46%**	**0.00%**	*0.15%*	**0.68%**	**0.53%**	**0.00%**	**0.15%**	**0.68%**
	0.00%	*9.12%*	*0.00%*	0.00%	*68.23%*	*0.44%*	*22.21%*	*100.00%*	*77.35%*	*0.44%*	*22.21%*	*100.00%*
	0.00%	0.14%	0.00%	0.00%	1.04%	0.21%	2.29%	0.68%	0.58%	0.05%	3.60%	0.68%
Total	5	242,075	11,718	59	238,233	7,658	35,396	535,144	483,182	29,501	22,461	535,144
	0.00%	**45.24%**	**2.19%**	**0.01%**	**44.52%**	**1.43%**	**6.61%**	**100.00%**	**90.29%**	**5.51%**	**4.20%**	**100.00%**
	0.00%	*45.24%*	*2.19%*	*0.01%*	*44.52%*	*1.43%*	*6.61%*	*100.00%*	*90.29%*	*5.51%*	*4.20%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	4	0	113	1	736	2,929	20,841	24,624	189,286
%	**0.01%**	**0.00%**	**0.38%**	**0.00%**	**2.49%**	**9.93%**	**70.65%**	**83.47%**	**35.37%**
	0.02%	*0.00%*	*0.46%*	*0.00%*	*2.99%*	*11.89%*	*84.64%*	*100.00%*	*54.97%*
	100.00%	0.00%	67.26%	100.00%	63.07%	50.34%	93.28%	83.47%	66.41%
Male	0	0	55	0	431	2,873	1,502	4,861	95,391
%	**0.00%**	**0.00%**	**0.19%**	**0.00%**	**1.46%**	**9.74%**	**5.09%**	**16.48%**	**17.83%**
	0.00%	*0.00%*	*1.13%*	*0.00%*	*8.87%*	*59.10%*	*30.90%*	*100.00%*	*50.97%*
	0.00%	0.00%	32.74%	0.00%	36.93%	49.38%	6.72%	16.48%	33.47%
Unknown	0	0	0	0	0	16	0	16	348
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.05%**	**0.00%**	**0.05%**	**0.07%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*	*100.00%*	*9.56%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.28%	0.00%	0.05%	0.12%
TOTAL	4	0	168	1	1,167	5,818	22,343	29,501	285,025
	0.01%	**0.00%**	**0.57%**	**0.00%**	**3.96%**	**19.72%**	**75.74%**	**100.00%**	**53.26%**
	0.01%	*0.00%*	*0.57%*	*0.00%*	*3.96%*	*19.72%*	*75.74%*	*100.00%*	*53.26%*
	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 18C

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

Number of Protocols with Enrollment Data: **0**

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Male	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Unknown	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%

Legend

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

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

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

Table 19A. Foreign Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2008 and Reported in FY2009: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	49,363	37,548		76.07%
%	53.01%	51.87%		
Males	43,441	34,829		80.18%
%	46.65%	48.11%		
Unknown	321	12		3.74%
%	0.34%	0.02%		
TOTAL	93,125	72,389	77.73%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	169

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

Number of Protocols with Enrollment Data: 97

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	20	5,605	30,909	7	4,389	4	270	41,204	40,577	376	251	41,204
	0.03%	**7.20%**	**39.72%**	**0.01%**	**5.64%**	**0.01%**	**0.35%**	**52.94%**	**52.14%**	**0.48%**	**0.32%**	**52.94%**
	0.05%	*13.60%*	*75.01%*	*0.02%*	*10.65%*	*0.01%*	*0.66%*	*100.00%*	*98.48%*	*0.91%*	*0.61%*	*100.00%*
	58.82%	57.81%	50.42%	46.67%	70.71%	100.00%	47.20%	52.94%	52.81%	79.16%	47.99%	52.94%
Male	12	4,083	30,389	8	1,678	0	139	36,309	36,108	99	102	36,309
	0.02%	**5.25%**	**39.05%**	**0.01%**	**2.16%**	**0.00%**	0.18%	**46.65%**	**46.40%**	**0.13%**	**0.13%**	**46.65%**
	0.03%	*11.25%*	*83.70%*	*0.02%*	*4.62%*	*0.00%*	0.38%	*100.00%*	*99.45%*	*0.27%*	*0.28%*	*100.00%*
	35.29%	42.11%	49.57%	53.33%	27.03%	0.00%	24.30%	46.65%	47.00%	20.84%	19.50%	46.65%
Unknown	2	7	2	0	140	0	163	314	144	0	170	314
	0.00%	**0.01%**	**0.00%**	0.00%	**0.18%**	**0.00%**	*0.21%*	**0.40%**	**0.19%**	**0.00%**	**0.22%**	**0.40%**
	0.64%	*2.23%*	*0.64%*	0.00%	*44.59%*	*0.00%*	*51.91%*	*100.00%*	*45.86%*	*0.00%*	*54.14%*	*100.00%*
	5.88%	0.07%	0.00%	0.00%	2.26%	0.00%	28.50%	0.40%	0.19%	0.00%	32.50%	0.40%
Total	34	9,695	61,300	15	6,207	4	572	77,827	76,829	475	523	77,827
	0.04%	**12.46%**	**78.76%**	**0.02%**	**7.98%**	**0.01%**	**0.73%**	**100.00%**	**98.72%**	**0.61%**	**0.67%**	**100.00%**
	0.04%	*12.46%*	*78.76%*	*0.02%*	*7.98%*	*0.01%*	*0.73%*	*100.00%*	*98.72%*	*0.61%*	*0.67%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	1	1	3	1	309	0	61	376	36,915
%	**0.21%**	**0.21%**	**0.63%**	**0.21%**	**65.05%**	**0.00%**	**12.84%**	**79.16%**	**47.43%**
	0.27%	*0.27%*	*0.80%*	*0.27%*	*82.18%*	*0.00%*	*16.22%*	*100.00%*	*89.59%*
	100.00%	100.00%	42.86%	100.00%	79.03%	0.00%	82.43%	79.16%	51.62%
Male	0	0	4	0	82	0	13	99	34,587
%	**0.00%**	**0.00%**	**0.84%**	**0.00%**	**17.26%**	**0.00%**	**2.74%**	**20.84%**	**44.44%**
	0.00%	*0.00%*	*4.04%*	*0.00%*	*82.83%*	*0.00%*	*13.13%*	*100.00%*	*95.26%*
	0.00%	0.00%	57.14%	0.00%	20.97%	0.00%	17.57%	20.84%	48.36%
Unknown	0	0	0	0	0	0	0	0	11
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.01%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*3.50%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%
TOTAL	1	1	7	1	391	0	74	475	71,513
	0.21%	**0.21%**	**1.47%**	**0.21%**	**82.32%**	**0.00%**	**15.58%**	**100.00%**	**91.89%**
	0.21%	*0.21%*	*1.47%*	*0.21%*	*82.32%*	*0.00%*	*15.58%*	*100.00%*	*91.89%*
	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%

Table 19C

Number of Protocols with Enrollment Data: 72

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	30	306	112	185	7,265	261	8,159	633
	0.20%	**2.00%**	**0.73%**	**1.21%**	**47.49%**	**1.71%**	**53.33%**	**4.14%**
	0.37%	*3.75%*	*1.37%*	*2.27%*	*89.04%*	*3.20%*	*100.00%*	*7.76%*
	68.18%	71.16%	59.57%	86.45%	54.34%	24.79%	53.33%	72.26%
Male	14	123	76	29	6,102	788	7,132	242
	0.09%	**0.80%**	**0.50%**	**0.19%**	**39.89%**	**5.15%**	**46.62%**	**1.58%**
	0.20%	*1.72%*	*1.07%*	*0.41%*	*85.56%*	*11.05%*	*100.00%*	*3.39%*
	31.82%	28.60%	40.43%	13.55%	45.64%	74.83%	46.62%	27.63%
Unknown	0	1	0	0	2	4	7	1
	0.00%	**0.01%**	**0.00%**	**0.00%**	**0.01%**	**0.03%**	**0.05%**	**0.01%**
	0.00%	*14.29%*	*0.00%*	*0.00%*	*28.57%*	*57.14%*	*100.00%*	*14.29%*
	0.00%	0.23%	0.00%	0.00%	0.01%	0.38%	0.05%	0.11%
Total	44	430	188	214	13,369	1,053	15,298	876
	0.29%	**2.81%**	**1.23%**	**1.40%**	**87.39%**	**6.88%**	**100.00%**	**5.73%**
	0.29%	*2.81%*	*1.23%*	*1.40%*	*87.39%*	*6.88%*	*100.00%*	*5.73%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

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

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	8,930	7,584		84.93%
%	85.25%	98.80%		
Males	1,545	92		5.95%
%	14.75%	1.20%		
Unknown	0	0		#DIV/0!
%	0.00%	0.00%		
TOTAL	10,475	7,676	73.28%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	4

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

Number of Protocols with Enrollment Data: 4

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	0	0	92	0	0	0	8,838	8,930	92	7,492	1,346	8,930
	0.00%	**0.00%**	**0.88%**	**0.00%**	**0.00%**	**0.00%**	**84.37%**	**85.25%**	**0.88%**	**71.52%**	**12.85%**	**85.25%**
	0.00%	*0.00%*	*1.03%*	*0.00%*	*0.00%*	*0.00%*	*98.97%*	*100.00%*	*1.03%*	*83.90%*	*15.07%*	*100.00%*
	0.00%	0.00%	59.35%	0.00%	0.00%	0.00%	85.64%	85.25%	59.35%	99.61%	48.09%	85.25%
Male	0	0	63	0	0	0	1,482	1,545	63	29	1,453	1,545
	0.00%	**0.00%**	**0.60%**	**0.00%**	**0.00%**	**0.00%**	14.15%	**14.75%**	**0.60%**	**0.28%**	**13.87%**	**14.75%**
	0.00%	*0.00%*	*4.08%*	*0.00%*	*0.00%*	*0.00%*	95.92%	*100.00%*	*4.08%*	*1.88%*	*94.05%*	*100.00%*
	0.00%	0.00%	40.65%	0.00%	0.00%	0.00%	14.36%	14.75%	40.65%	0.39%	51.91%	14.75%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	0.00%	**0.00%**	**0.00%**	*0.00%*	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	155	0	0	0	10,320	10,475	155	7,521	2,799	10,475
	0.00%	**0.00%**	**1.48%**	**0.00%**	**0.00%**	**0.00%**	**98.52%**	**100.00%**	**1.48%**	**71.80%**	**26.72%**	**100.00%**
	0.00%	*0.00%*	*1.48%*	*0.00%*	*0.00%*	*0.00%*	*98.52%*	*100.00%*	*1.48%*	*71.80%*	*26.72%*	*100.00%*
	0.00%	0.00%	100.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
Female	0	0	0	0	0	0	7,492	7,492	7,584
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**99.61%**	**99.61%**	**72.40%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*84.93%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	99.61%	99.61%	98.80%
Male	0	0	0	0	0	0	29	29	92
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.39%**	**0.39%**	**0.88%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*5.95%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.39%	0.39%	1.20%
Unknown	0	0	0	0	0	0	0	0	0
%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	0	7,521	7,521	7,676
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**100.00%**	**73.28%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*100.00%*	*73.28%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%

Table 20C

Number of Protocols with Enrollment Data: **0**

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

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**
Female	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Male	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Unknown	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**100.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%

Legend

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

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

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