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

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

NIH Tracking/Inclusion Committee

Vivian W. Pinn, M.D., Co-Chair
Office of Research on Women's Health

Carl Roth, Ph.D., LL.M., Co-Chair
National Heart, Lung, and Blood Institute

Angela C. Bates, M.B.A.
Office of Research on Women's Health

Robin Wagner, Ph.D.
Liaison, Office of Extramural Research

Kim Jarema
Liaison, NIH Clinical Center

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Preface

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

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

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

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

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

Historical Perspective

The establishment and implementation of policies for the inclusion of women and minorities in clinical research funded by the National Institutes of Health (NIH) has its origins in the women's health movement. Following the issuance of the report of the Public Health Service Task Force on Women's Health in 1985¹, the NIH established a policy in 1986 for the inclusion of women in clinical research. This policy, which *urged* the inclusion of women, was first published in the NIH Guide to Grants and Contracts in 1987². Later that year, minority and other scientists at the NIH recognized the need to address the inclusion of minority populations. Therefore, in a later 1987 version of the NIH guide, a policy *encouraging* the inclusion of minorities in clinical studies was first published.

In order to ensure that the policies for inclusion were firmly implemented by NIH, the Congress made what had previously been policy into Public Law, through a section in the NIH Revitalization Act of 1993 (PL 103-43)³ entitled *Women and Minorities as Subjects in Clinical Research*. In 1994, NIH revised its inclusion policy to be in compliance with the statutory language. The Revitalization Act essentially reinforced the existing NIH policies, but with four major differences:

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

Revised inclusion guidelines developed in response to this law were published in the *Federal Register*⁴ in March 1994, and they became effective in September 1994. The result was that NIH could not and would not fund any grant, cooperative agreement or contract or support any intramural project to be conducted or funded in Fiscal Year 1995 and thereafter which did not comply with this policy.

Strategies to ensure uniform implementation 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 the 1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled *Women's Health - NIH Has Increased Its Efforts to Include Women in Research*.⁵ It concluded that in the past decade, NIH had made significant progress in implementing a strengthened policy on including women in clinical research.

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

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

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

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

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

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

NIH AGGREGATE POPULATION DATA REPORTED IN FY2007 and FY2008

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

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

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

NIH CLINICAL RESEARCH: Fiscal Years 2007 and 2008

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

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

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

NIH Defined Phase III Clinical Research: FY2007 and FY2008

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

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

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

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

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

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

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

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

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2007 and 2008

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

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

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

NIH Defined Phase III Extramural Clinical Research: FY2007 and FY2008

In FY2007 there were 711 extramural Phase III clinical research protocols, of which 617 protocols reported human subject participation. (*Table 13A*) A total of 547,687 participants were enrolled in extramural Phase III research protocols of which 55.10% were women, 41.83% were men and 3.07% did not provide sex identification. (*Table 14A*)

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

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

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

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

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2007 and 2008

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

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

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

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

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

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

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

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

NIH Defined Phase III Intramural Clinical Research: FY2007 and FY2008

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

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

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

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

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY1995 – FY2008

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

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

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

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

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

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

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

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

***Fiscal Year 2008 Summary Reports
Fourteen -year Trend Summary Reports***

Table 1. NIH Fourteen Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY 1995-2008: Enrollment by Race and Ethnicity

1A. Fourteen YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER AND MINORITY CATEGORIES IN ALL PROTOCOLS (Old + New Forms)

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

Total Minority Enrollment Reported by Year

Sex/Gender Enrollment by Year Reported

Table 1A Comments:

- Table 1A summarizes enrollment by sex/gender and minority race/ethnicity categories for the fourteen year reporting period (1995-2008). The data are compiled from Tables 1B, 1C and 1D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 1B) and the NEW Enrollment Form (Tables 1C and 1D).
- The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

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

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

Table 1. NIH Fourteen Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY

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

NOTE 2: Data from Tables 1B, 1C and 1D are combined to provide the summary data in Table 1A.

1B. 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/Ot her		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%		

ORIENTATION TO TABLES 1C and 1D.

1. The New Form consists of Parts A and B (Tables 1C and 1D) for reporting years 2002-2008. This Form is provided as part of the annual progress report.
2. Table 1C displays the New Form Part A for reporting separate race and ethnicity data.
3. Table 1D 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.

1C. New Form Part A: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity													
Total of All Subjects by Race										Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total*	Not Hispanic	Hispanic or Latino**	Unknown /Not Reported	Total*
2002	2001	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%

1D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

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

* These totals must agree.

**These totals must agree.

1E. Comparison of Domestic and Foreign Enrollment & Protocols with Total Enrollment for the period FY2002-2008

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

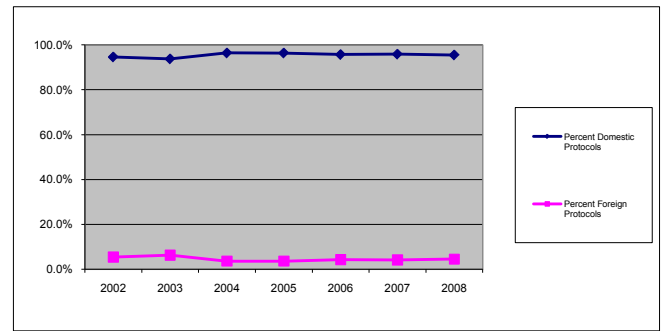
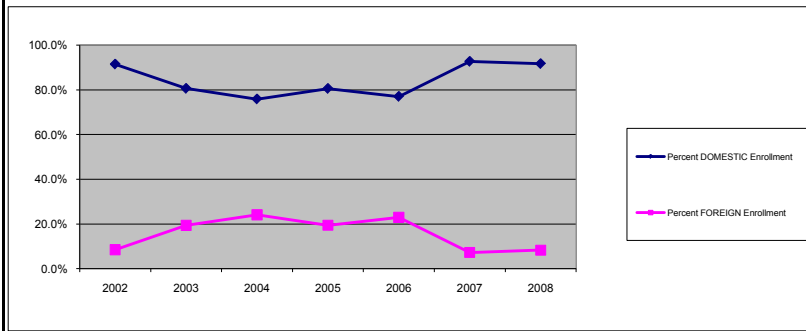


Table 1E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increased overall from FY2002-2008.
2. The Percent Domestic Enrollment decreased to approximately 91.7%, while the Percent Foreign Enrollment increased to approximately 8.3%.
3. The vast majority of protocols are domestic protocols (approximately 93-96%), while foreign protocols make up approximately 3-6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

1F. Comparison of Domestic and Foreign Minority Participation for FY 2002-2008

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%

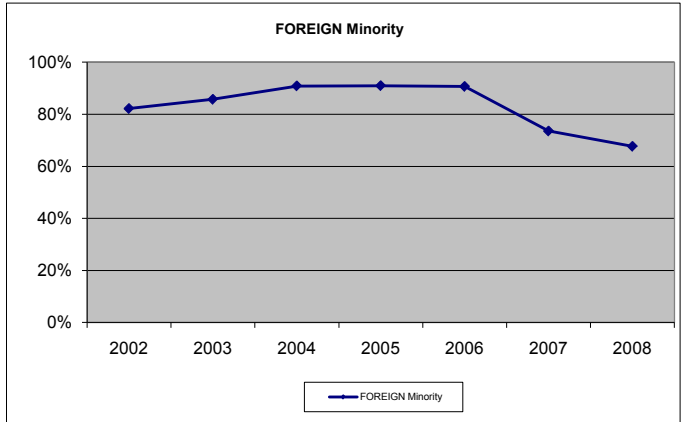
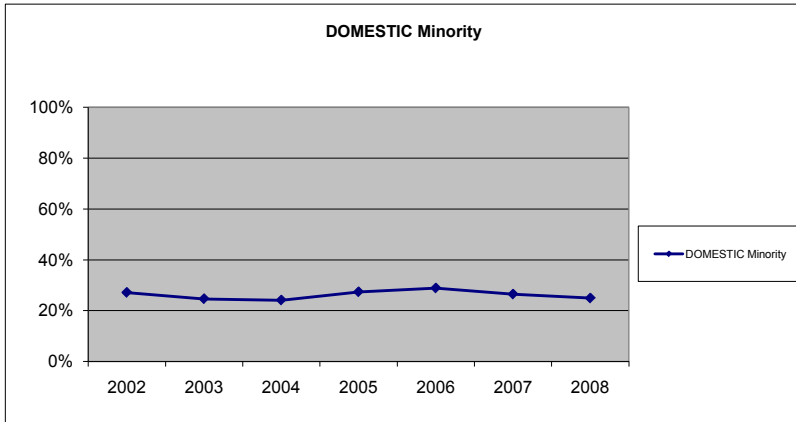
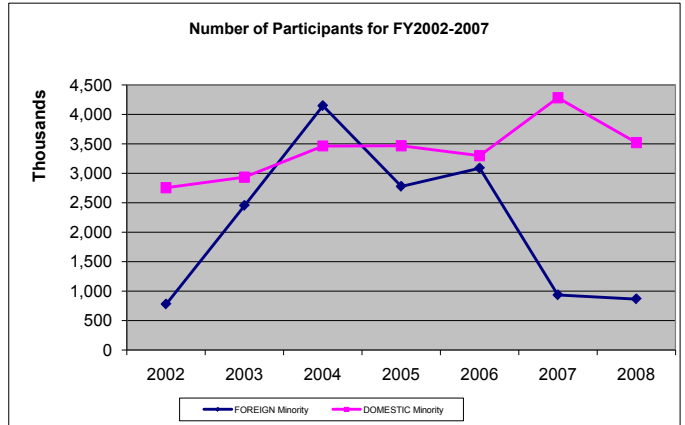


Table1F Comments:

- Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment.
- Foreign Minority Enrollment has varied from 67.7% to 90.9% of Total Foreign Enrollment, reflecting that most of the foreign research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary minority data used in this report.
- The Total Minority Enrollment reported in FY2008 was 80.3% Domestic and 19.7% Foreign. The small percentage of foreign protocols account for a significant proportion (19.7%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

Table 2. Summary of NIH Clinical Research Reported In FY2007: 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	10,914	10,463	95.9%	451	4.1%
%	70.1%	70.5%		62.6%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,653	4,383	94.2%	270	5.8%
	29.9%	29.5%		37.4%	
Total Number of Protocols	15,567	14,846	95.4%	721	4.6%
%	100.0%	100.0%		100.0%	

See Table 2A comments on next page.

2B. ENROLLMENT REPORTED	Total All Clinical Studies*	Domestic	%	Foreign	%
Females Enrolled	10,152,589	9,397,957	92.6%	754,632	7.4%
%	58.2%	58.1%		59.5%	
Males Enrolled	6,887,791	6,389,817	92.8%	497,974	7.2%
%	39.5%	39.5%		39.3%	
Sex of Subjects is Unknown	408,078	392,814	96.3%	15,264	3.7%
%	2.3%	2.4%		1.2%	
Total Subjects Enrolled	17,448,458	16,180,588	92.7%	1,267,870	7.3%
%	100.0%	100.0%		100.0%	

See Table 2B comments on next page.

2C. MINORITY ENROLLMENT REPORTED	Total All Clinical Studies*	Domestic	%	Foreign	%
Minority Total**	5,216,434	4,283,738	82.1%	932,696	17.9%
% Minority Enrollment	29.9%	26.5%		73.6%	

See Table 2C comments on next page.

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

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

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

COMMENTS

Table 2. Summary of NIH Clinical Research Reported in FY2007: Total Number of Protocols and Enrollment by Sex and Domestic versus Foreign Protocols

Table 2A: Total Number of Protocols

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

Total Domestic Protocols

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

Total Foreign Protocols

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

Table 2B: Total Enrollment Reported

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

Total Domestic Enrollment Reported

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

Total Foreign Enrollment

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

Table 2C: Minority Enrollment Reported

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

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

3A. 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%	

See Table 3A comments on next page.

3B. 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%	

See Table 3B comments on next page.

3C. 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%	

See Table 3C comments on next page.

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

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

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

COMMENTS

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

Table 3A: Total Number of Protocols

1. The total number of protocols reported in the NIH database in FY2008 was 15,598; of these, 11,045 (70.8%) reported subject enrollment.
2. Subsequent tables reporting "Enrollment Reported" are based on the 11,045 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting "Enrollment Reported."

Total Domestic Protocols

4. Domestic protocols made up the vast majority of protocols (14,875; 95.4%); of these, 10,548 (70.9%) reported domestic subject enrollment.
5. Clinical research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Total Foreign Protocols

6. Foreign protocols account for only a small percentage of protocols (723; 4.6%); of these, 497 (68.7%) reported foreign subject enrollment.

Table 3B: Total Enrollment Reported

1. The total "Enrollment Reported" in the NIH database in FY2008 was 15,412,355 subjects in 11,045 protocols with enrollment.
2. Females made up 60.0% (9.2M) of total subjects enrolled, while Males made up 38.9% (6.0M), with 1.1% unknown.
3. Total Enrollment Reported decreased by 11.7% in the past year (17,448,458 in FY2007; 15,412,355 in FY2008).

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 14,134,627 (91.7%)
5. Females made up 60.2% (8.5M) of the domestic subjects enrolled, while Males made up 38.6% (5.5M) with 1.2% (0.2M) unknown.

Total Foreign Enrollment

6. The total Foreign Enrollment reported was 1,277,728 (8.3%).
7. Females made up 57.1% (0.73M) of the foreign subjects enrolled, while males made up 42.3% (0.54M) with 0.7% unknown (0.008M).

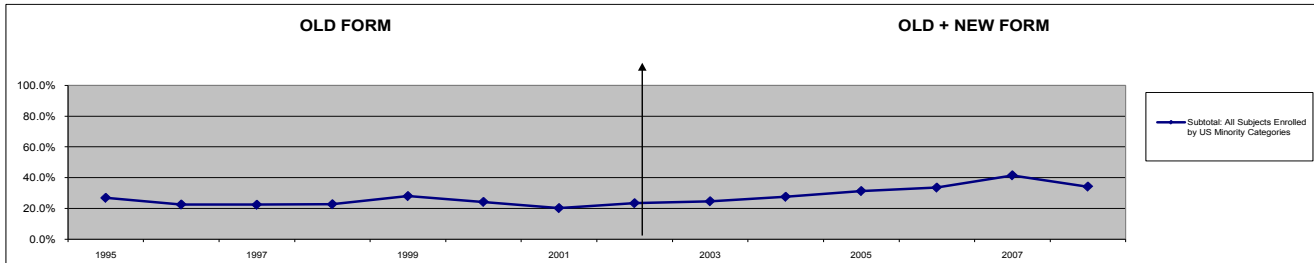
Table 3C: Minority Enrollment Reported

1. Minorities made up 28.5% (4.4M) of the total subjects enrolled.
2. Minorities made up 24.9% (3.5M) of the total Domestic Enrollment.
3. Minority Enrollment Reported decreased 16% in the past year (5,216,434 in FY2007; 4,386,636 in FY2008). The small percentage of foreign protocols (4.5%) account for 19.7% of minority enrollment.

Table 4: Fourteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2008: Enrollment by Race and Ethnicity

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

Total Phase III Enrollment by Year Reported



Sex/Gender Phase III Enrollment by Year Reported

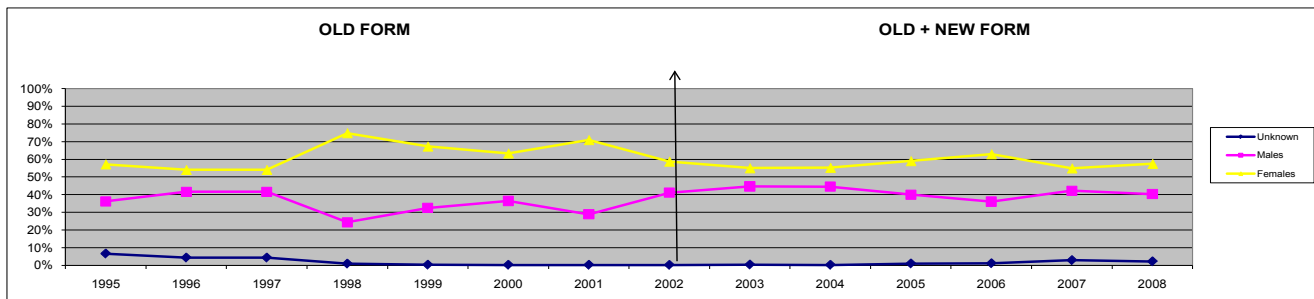


Table 4A Comments:

1. Table 4A summarizes enrollment by sex/gender and minority race/ethnicity categories for the fourteen year reporting period (1995-2008). The data are compiled from Tables 4B, 4C and 4D below, which provide the detailed distributions by sex/gender and r

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 Stand

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

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

Table 4: Fourteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2008: 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 report

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 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 of 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%	

ORIENTATION TO TABLES 4C and 4D.

1. The New Form consists of Parts A and B (Tables 4C and 4D) for reporting years 2002-2008. This Form is provided as part of the annual
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 Separate Race and Ethnicity

FY Reported	FY Funded	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
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
	%	0.5%	3.2%	26.4%	0.3%	58.4%	1.2%	9.9%	100.0%	78.5%	9.6%	12.0%	100.0%
2004	2003	1,385	4,385	43,721	611	106,793	4,419	5,657	169,992	145,742	13,435	7,905	169,992
	%	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	15,066	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%

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%	

* These totals must agree

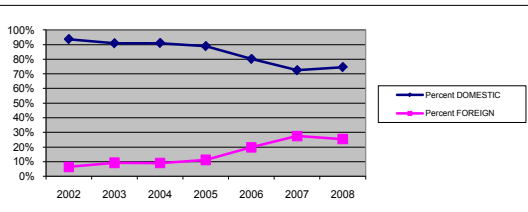
** These totals must agree

Table 4: Fourteen Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2008: Enrollment by Race and Ethnicity

4E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2008

FY Reported	FY Funded	ENROLLMENT				PROTOCOLS					
		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%

Percentage of Phase III Domestic and Foreign Enrollment



Number of Phase III Domestic and Foreign protocols

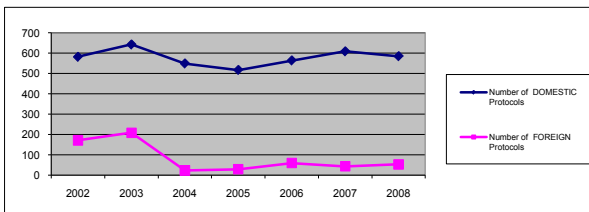


Table 4E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increased overall from FY 2002 - 2008.
2. The Percent Domestic enrollment increased to approximately 74.6%, while Foreign enrollment decreased to approximately 25.4% in 2008.
3. The vast majority of protocols in FY 2004 - 2008 are domestic protocols.

4F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2008

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%

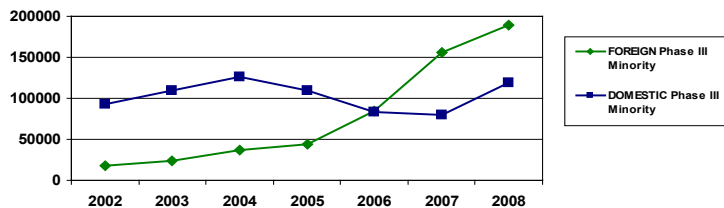


Table 8F Comments:

1. The Total Phase III Minority Foreign Participants increased from 60.4% in 2002 to 93.7% in 2008.
2. The Total Phase III Minority Domestic Participants varied from 20.2% to 25.4% between 2002 and 2008.
3. The Total Minority Enrollment reported in FY2008 was 80.3% Domestic and 19.7% Foreign (see Table 1). The small percentage of foreign protocols (4.5%) account for a significant proportion (19.7%) of the Total Minority Enrollment, as shown by comparing b

Table 5. Summary of NIH Phase III Clinical Research Reported In FY2007: 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	653	609	93.3%	44	6.7%
%	87.2%	87.6%		81.5%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	96	86	89.6%	10	10.4%
%	12.8%	12.4%		18.5%	
Total Number of Protocols	749	695	92.8%	54	7.2%
%	100.0%	100.0%		100.0%	

See Table 5A comments on next page.

5B. ENROLLMENT REPORTED	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Females Enrolled	324,694	228,289	70.3%	96,405	29.7%
%	54.9%	53.3%		59.2%	
Males Enrolled	249,633	183,878	73.7%	65,755	26.3%
%	42.2%	42.9%		40.4%	
Sex of Subjects is Unknown	16,832	16,273	96.7%	559	0.0%
%	2.8%	3.8%		0.3%	
Total Subjects Enrolled	591,159	428,440	72.5%	162,719	27.5%
%	100.0%	100.0%		100.0%	

See Table 5B comments on next page.

5C. MINORITY ENROLLMENT REPORTED**	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Minority Total for all Phase III studies	244,932	88,339	36.1%	156,593	63.9%
%	41.4%	20.6%		96.2%	

See Table 5C on next page.

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

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

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

COMMENTS

Table 5. Summary of NIH Phase III Clinical Research Reported in FY2007: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

Table 5A: Total Number of Protocols

1. The total number of NIH defined Phase III Clinical Protocols reported in the NIH database in FY2007 was 749; of these, 653 (87.2%) reported subject enrollment. Of these, the remainder are new clinical studies or studies pending enrollment.
2. Subsequent tables reporting "Enrollment Reported" are based on the 653 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting "Enrollment Reported"

Total Domestic Protocols:

4. Domestic protocols made up the majority of protocols with a total of 695 (92.8%); of these, 609 (87.6%) reported domestic subject enrollment.
5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Total Foreign Protocols

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

Table 5B: Total Enrollment Reported

1. The total "Enrollment Reported" in NIH Defined Phase III Protocols in the NIH database in FY2007 was 591,159 subjects in 653 protocols.
2. Females 324,649 made up (54.9%) of the total subjects enrolled, while Males 249,633 made up (42.2%) with Unknowns 16,832 making up (2.8%).
3. Minorities 244,932 made up (41.4%) of the total subjects enrolled 591,159.

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 428,440 (72.5%).
5. Females 228,289 made up (53.3%) of the Domestic subjects enrolled, while Males 183,878 made up 42.9% with Unknowns 16,273 making up (3.8%).

Total Foreign Enrollment Reported

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

Table 5C: Minority Enrollment Reported

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

Table 6. Summary of NIH Phase III Clinical Research Reported In FY2008: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
6A. PROTOCOLS REPORTED					
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%	

See Table 6A comments on next page.

	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
6B. ENROLLMENT REPORTED					
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%	

See Table 6B comments on next page.

	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
6C. MINORITY ENROLLMENT REPORTED**					
Minority Total for all Phase III studies	308,433	119,582	38.8%	188,851	61.2%
	38.9%	20.2%		93.7%	

See Table 6C on next page.

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

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

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

COMMENTS

Table 6. Summary of NIH Phase III Clinical Research Reported in FY2007: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

Table 6A: Total Number of Protocols

1. The total number of NIH defined Phase III Clinical Protocols reported in the NIH database in FY2008 was 726; of these, 639 (88.0%) reported subject enrollment.
2. Subsequent tables reporting "Enrollment Reported" are based on the 639 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting "Enrollment Reported"

Total Domestic Protocols:

4. Domestic protocols made up the majority of protocols with a total of 664 (91.5%); of these, 585 (91.5%) reported domestic subject enrollment.
5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Total Foreign Protocols

6. Total Foreign Protocols increased from 44 in FY2007 to 54 in FY2008.

Table 6B: Total Enrollment Reported

1. The total "Enrollment Reported" in NIH Defined Phase III Protocols in the NIH database in FY2008 was 792,578 subjects in 639 protocols.
2. Females made up 57.5% (455,590) of the total subjects enrolled, while Males made up 40.3% (319,754), with 2.2% (17,234) unknown.
3. Minorities made up 38.9% (308,433) of the total subjects enrolled (792,578).

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 591,105 (74.6%)
- 5 Females made up 58.9% (347,982) of the Domestic subjects enrolled, while Males made up 38.3% (226,266), with 2.9% (16,857) unknown.

Total Foreign Enrollment Reported

6. The total Foreign Enrollment Reported was 201,473 (25.4%).
7. Females made up 53.4% (107,608) of the Foreign subjects enrolled, while Males made up 46.4% (93,488), with 0.2% (377) unknown.
8. Total Foreign Enrollment increased by 24% (162,719 in FY2007; 201,473 in FY2008).

Table 6C: Minority Enrollment Reported

1. Total Minority Enrollment was 38.9% (308,433) of Total Enrollment Reported (792,578).
2. Minorities made up 20.2% (119,582) of the Total Domestic Enrollment (591,105).
3. Minorities made up 93.7% (188,851) - the vast majority - of the Total Foreign Enrollment (201,473).
4. Total Minority Enrollment was 38.86% Domestic and 61.2% Foreign.

Table 7. Overview of NIH Extramural and Intramural Clinical Research Reported in FY2007: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

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

See Table 7A comments on next page.

7B. ENROLLMENT REPORTED	Total All Clinical Studies	Domestic				Foreign			
		Extramural	%	Intramural	%	Extramural	%	Intramural	%
In Protocols reporting females only	9,000,648	6,830,795	75.9%	1,884,141	20.9%	142,737	1.6%	142,975	1.6%
%	51.6%	52.2%		60.8%		15.7%		40.1%	
In Protocols reporting males only	377,803	335,655	88.8%	3,203	0.8%	11,998	3.2%	26,947	7.1%
%	2.2%	2.6%		0.1%		1.3%		7.5%	
In Protocols excluding female-only and male-only enrollment protocols	8,070,007	5,913,901	73.3%	1,212,893	15.0%	756,196	9.4%	187,017	2.3%
%	46.3%	45.2%		39.1%		83.0%		52.4%	
Enrollment Totals for all studies	17,448,458	13,080,351	75.0%	3,100,237	17.8%	910,931	5.2%	356,939	2.0%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

See Table 7B Comments on next page.

7C. MINORITY ENROLLMENT REPORTED**		Domestic				Foreign			
		Extramural	%	Intramural	%	Extramural	%	Intramural	%
Minority Totals for all studies	5,216,434	3,651,722	70.0%	632,016	12.1%	746,278	14.3%	186,418	3.6%
% Minority enrollment	29.9%	27.9%		20.4%		81.9%		52.2%	

See Table 7C comments on next page.

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

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

COMMENTS

Table 7: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2006: Number of Sex-Specific Protocols and Domestic versus Foreign Protocols

Table 7A: Total Number of Protocols with Enrollment

1. Female Only Protocols: There were 1,340 protocols reporting females only, representing 12.3% (1,340/10,914) of protocols with enrollment.

1,207 (90.1%) were Extramural Protocols; 132 (9.9%) were NIH Intramural Protocols.
1,288 (96.1%) were Domestic Protocols; 52 (3.9%) were Foreign Protocols.

2. Male Only Protocols: There were 517 protocols reporting males only, representing 4.7% (516/10,914) of protocols with enrollment.

485 (93.8%) were Extramural Protocols; 32 (6.2%) were NIH Intramural Protocols.
497 (96.1%) were Domestic Protocols; 20 (3.9%) were Foreign Protocols.

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 9,057 protocols reporting both female and male participants representing 83.0% (9,057/10,914) of protocols with enrollment.

7,760 (84.7%) were Extramural protocols; 1,384 (15.3%) were NIH Intramural protocols.
8,678 (95.8%) were Domestic Protocols; 379 (4.2%) were Foreign Protocols.

Table 7B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 9.0 M females, representing 51.6% of total enrollment

7.0M (77.5%) were in Extramural protocols; 2.03 (22.5%) were in NIH Intramural protocols.
8.7M (96.8%) were Domestic protocols, 0.28 (3.2%) were Foreign Protocols.

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

0.35M (92.0%) were in Extramural protocols; 0.3 (8.0%) were in NIH Intramural protocols.
0.34M (89.7%) were Domestic protocols; 0.38M (10.3%) were Foreign protocols.

3. In Protocols reporting Both Females and Males (excluding sex-specific studies): There were approximately 8.1M subjects, representing 46.3% of total enrollment

6.6M (82.7%) were in Extramural protocols; 1.4M (17.3%) were in NIH Intramural protocols.
7.13M (88.3%) were Domestic protocols, 0.94M (11.7%) were Foreign protocols.

Table 7C Minority Enrollment Reported

Total Minority Enrollment: 29.9% of Total Enrollment (5.2M/17.4M)

Total Domestic Minority Enrollment: 4.3M (82.1%) of Total Minority Enrollment (4,283,738/5,216,434).

Total Foreign Minority Enrollment: 0.93M (17.9%) of Total Minority Enrollment (932,696/5,216,434).

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

Total Foreign Minority Enrollment (Extramural + Intramural): 0.93M (5.3%) of Total Enrollment (932,696/17,448,458).

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

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

Table 8. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

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

Total Number of Protocols with Enrollment Data:	9,362
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8B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 8,713			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	86,249	799,997	996,531	30,436	5,456,346	160,305	847,000	8,376,864	6,917,630	683,000	776,234	8,376,864
	0.64%	5.93%	7.39%	0.23%	40.46%	1.19%	6.28%	62.12%	51.30%	5.07%	5.76%	62.12%
	1.03%	9.55%	11.90%	0.36%	65.14%	1.91%	10.11%	100.00%	82.58%	8.15%	9.27%	100.00%
	69.75%	68.38%	56.12%	57.28%	63.17%	60.63%	58.00%	62.12%	63.28%	64.02%	52.22%	62.12%
Male	36,876	368,138	771,181	22,345	3,157,379	102,084	291,234	4,749,237	3,985,057	378,293	385,887	4,749,237
	0.27%	2.73%	5.72%	0.17%	23.41%	0.76%	2.16%	35.22%	29.55%	2.81%	2.86%	35.22%
	0.78%	7.75%	16.24%	0.47%	66.48%	2.15%	6.13%	100.00%	83.91%	7.97%	8.13%	100.00%
	29.82%	31.46%	43.43%	42.05%	36.55%	38.61%	19.94%	35.22%	36.46%	35.46%	25.96%	35.22%
Unknown	526	1,863	7,854	355	23,725	2,003	322,015	358,341	28,501	5,547	324,293	358,341
	0.00%	0.01%	0.06%	0.00%	0.18%	0.01%	2.39%	2.66%	0.21%	0.04%	2.40%	2.66%
	0.15%	0.52%	2.19%	0.10%	6.62%	0.56%	89.86%	100.00%	7.95%	1.55%	90.50%	100.00%
	0.43%	0.16%	0.44%	0.67%	0.27%	0.76%	22.05%	2.66%	0.26%	0.52%	21.82%	2.66%
Total	123,651	1,169,998	1,775,566	53,136	8,637,450	264,392	1,460,249	13,484,442	10,931,188	1,066,840	1,486,414	13,484,442
	0.92%	8.68%	13.17%	0.39%	64.05%	1.96%	10.83%	100.00%	81.07%	7.91%	11.02%	100.00%
	0.92%	8.68%	13.17%	0.39%	64.05%	1.96%	10.83%	100.00%	81.07%	7.91%	11.02%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	19,600	5,562	17,069	2,574	328,520	55,722	253,953	683,000	2,655,991
	1.84%	0.52%	1.60%	0.24%	30.79%	5.22%	23.80%	64.02%	19.70%
	2.87%	0.81%	2.50%	0.38%	48.10%	8.16%	37.18%	100.00%	31.71%
	55.79%	75.35%	60.43%	60.52%	68.30%	57.60%	61.33%	64.02%	62.03%
Male	15,372	1,784	11,091	1,665	151,846	40,563	155,972	378,293	1,608,442
	1.44%	0.17%	1.04%	0.16%	14.23%	3.80%	14.62%	35.46%	11.93%
	4.06%	0.47%	2.93%	0.44%	40.14%	10.72%	41.23%	100.00%	33.87%
	43.76%	24.17%	39.26%	39.15%	31.57%	41.93%	37.67%	35.46%	37.56%
Unknown	159	36	88	14	652	452	4,146	5,547	17,399
	0.01%	0.00%	0.01%	0.00%	0.06%	0.04%	0.39%	0.52%	0.13%
	2.87%	0.65%	1.59%	0.25%	11.75%	8.15%	74.74%	100.00%	4.86%
	0.45%	0.49%	0.31%	0.33%	0.14%	0.47%	1.00%	0.52%	0.41%
TOTAL	35,131	7,382	28,248	4,253	481,018	96,737	414,071	1,066,840	4,281,832
	3.29%	0.69%	2.65%	0.40%	45.09%	9.07%	38.81%	100.00%	31.75%
	3.29%	0.69%	2.65%	0.40%	45.09%	9.07%	38.81%	100.00%	31.75%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 8

8C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	1,804	7,845	30,985	19,853	198,153	17,141	275,781	60,487
	0.36%	1.55%	6.11%	3.92%	39.10%	3.38%	54.41%	11.93%
	<i>0.65%</i>	<i>2.84%</i>	<i>11.24%</i>	<i>7.20%</i>	<i>71.85%</i>	<i>6.22%</i>	<i>100.00%</i>	<i>21.93%</i>
	49.10%	53.55%	52.52%	50.52%	56.14%	45.98%	54.41%	51.87%
Male	1,727	6,638	27,428	18,942	153,077	14,846	222,658	54,735
	0.34%	1.31%	5.41%	3.74%	30.20%	2.93%	43.93%	10.80%
	<i>0.78%</i>	<i>2.98%</i>	<i>12.32%</i>	<i>8.51%</i>	<i>68.75%</i>	<i>6.67%</i>	<i>100.00%</i>	<i>24.58%</i>
	47.01%	45.31%	46.50%	48.20%	43.37%	39.82%	43.93%	46.94%
Unknown	143	168	578	501	1,717	5,294	8,401	1,390
	0.028%	0.03%	0.11%	0.10%	0.34%	1.04%	1.66%	0.27%
	<i>1.70%</i>	<i>2.00%</i>	<i>6.88%</i>	<i>5.96%</i>	<i>20.44%</i>	<i>63.02%</i>	<i>100.00%</i>	<i>16.55%</i>
	3.89%	1.15%	0.98%	1.27%	0.49%	14.20%	1.66%	1.19%
Total	3,674	14,651	58,991	39,296	352,947	37,281	506,840	116,612
	0.72%	2.89%	11.64%	7.75%	69.64%	7.36%	100.00%	23.01%
	<i>0.72%</i>	<i>2.89%</i>	<i>11.64%</i>	<i>7.75%</i>	<i>69.64%</i>	<i>7.36%</i>	<i>100.00%</i>	<i>23.01%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

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

Race

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

Ethnicity

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

Table 9: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2008: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

	Total All Clinical Studies	Domestic				Foreign			
		Extramural	%	Intramural	%	Extramural	%	Intramural	%
9A. PROTOCOLS REPORTED									
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%	

See Table 9A comments on next page.

	Total All Clinical Studies	Domestic				Foreign			
		Extramural	%	Intramural	%	Extramural	%	Intramural	%
9B. ENROLLMENT REPORTED									
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%	

See Table 9B Comments on next page.

	Total All Clinical Studies	Domestic				Foreign			
		Extramural	%	Intramural	%	Extramural	%	Intramural	%
9C. MINORITY ENROLLMENT REPORTED**									
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 Table 9C comments on next page.

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

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

COMMENTS

Table 9: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2008: Number of Sex-Specific Protocols and Domestic versus Foreign Protocols

Table 9A: Total Number of Protocols with Enrollment

- 1. Female Only Protocols: There were 1,272 protocols reporting females only, representing 11.5% (1,272/11,045) of protocols with enrollment.**
89.9% were Extramural Protocols (1,104+40); 10.1% were NIH Intramural Protocols (121+7).
96.3% were Domestic Protocols (1,104+121); 3.7% were Foreign Protocols (40+7)
- 2. Male Only Protocols: There were 529 protocols reporting males only, representing 4.8% (529/11,045) of protocols with enrollment.**
94.1% were Extramural Protocols (480+18); 5.9% were NIH Intramural Protocols (26+5).
95.7% were Domestic Protocols (480+26); 4.3% were Foreign Protocols (18+5)
- 3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 9,244 protocols reporting both female and male participants representing 83.7% (9,244/11,045) of protocols with enrollment.**
83.7% were Extramural projects (7,387+352); 16.3% were NIH Intramural projects (1,430+75)
95.4% were Domestic Protocols (7,387+1,430); 4.6% were Foreign Protocols (352+75)

Table 9B Total Enrollment Reported

- 1. In Female Only Protocols: There were approximately 7.5M females, representing 48.7% of total enrollment**
92.6% were in Extramural projects; 7.4% were in NIH Intramural projects
96.0% were Domestic protocols, 4.0% were Foreign protocols
- 2. In Male Only Protocols: There were approximately 361,434 males, representing 2.3% of total enrollment**
90.4% were in Extramural projects; 9.6% were in NIH Intramural projects
89.1% were Domestic protocols; 10.9% were Foreign protocols
- 3. In Protocols reporting Both Females and Males (excluding sex-specific studies): There were approximately 7.5M subjects, representing 48.9% of total enrollment**
70.3% were in Extramural projects; 29.7% were in NIH Intramural projects
87.6% were Domestic protocols, 12.4% were Foreign protocols

Table 9C Minority Enrollment Reported

Total Minority Enrollment: 28.7% of Total Enrollment (4.4M/15.4M)

Total Domestic Minority Enrollment: 80.4% of Minority Enrollment (3,551,825/4,416,770)

Total Foreign Minority Enrollment: 19.6% of Minority Enrollment (864,945/4,416,770)

Total Domestic Minority Enrollment (Extramural + Intramural): 23.0% of Total Enrollment (3,551,825/15,412,355)

Total Foreign Minority Enrollment (Extramural + Intramural): 5.6% of Total Enrollment (864,945/15,412,355)

Total Minority Enrollment in all Extramural projects (Domestic + Foreign): 24.0% of Total Enrollment (3,695,589/15,412,355)

Total Minority Enrollment in all Intramural projects (Domestic + Foreign): 4.7% of Total Enrollment (721,181/15,412,355)

Table 10. Aggregate Enrollment Data for Extramural Research 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	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

10B. 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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
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 10

Number of Protocols with Enrollment Data:

10C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
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%
	<i>0.40%</i>	<i>2.38%</i>	<i>8.45%</i>	<i>4.21%</i>	<i>81.35%</i>	<i>3.21%</i>	<i>100.00%</i>	<i>15.44%</i>
	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%
	<i>0.32%</i>	<i>1.82%</i>	<i>10.94%</i>	<i>6.57%</i>	<i>74.64%</i>	<i>5.72%</i>	<i>100.00%</i>	<i>19.64%</i>
	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%
	<i>0.00%</i>	<i>3.39%</i>	<i>1.04%</i>	<i>0.52%</i>	<i>45.43%</i>	<i>49.61%</i>	<i>100.00%</i>	<i>4.96%</i>
	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%
	<i>0.38%</i>	<i>2.22%</i>	<i>9.13%</i>	<i>4.87%</i>	<i>79.44%</i>	<i>3.95%</i>	<i>100.00%</i>	<i>16.61%</i>
	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 11. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

11A. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	4,435,292	1,645,545		37.10%
%	46.45%	50.36%		
Males	4,761,326	1,606,976		33.75%
%	49.87%	49.18%		
Unknown	350,892	14,743		4.20%
%	3.68%	0.45%		
TOTAL	9,547,510	3,267,264	34.22%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 7,651

11B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 7,158			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	43,409	408,811	666,263	28,253	2,635,011	134,098	338,551	4,254,396	3,523,627	395,681	335,088	4,254,396
	0.47%	4.45%	7.26%	0.31%	28.71%	1.46%	3.69%	46.36%	38.39%	4.31%	3.65%	46.36%
	1.02%	9.61%	15.66%	0.66%	61.94%	3.15%	7.96%	100.00%	82.82%	9.30%	7.88%	100.00%
	54.07%	53.12%	47.06%	55.61%	46.35%	57.38%	35.94%	46.36%	47.43%	51.37%	34.26%	46.36%
Male	36,344	359,148	744,527	22,194	3,034,321	98,583	285,602	4,580,719	3,883,627	369,165	327,927	4,580,719
	0.40%	3.91%	8.11%	0.24%	33.06%	1.07%	3.11%	49.91%	42.32%	4.02%	3.57%	49.91%
	0.79%	7.84%	16.25%	0.48%	66.24%	2.15%	6.23%	100.00%	84.78%	8.06%	7.16%	100.00%
	45.27%	46.67%	52.59%	43.69%	53.37%	42.18%	30.32%	49.91%	52.27%	47.92%	33.53%	49.91%
Unknown	526	1,648	5,062	355	15,996	1,028	317,876	342,491	22,055	5,483	314,953	342,491
	0.01%	0.02%	0.06%	0.00%	0.17%	0.01%	3.46%	3.73%	0.24%	0.06%	3.43%	3.73%
	0.15%	0.48%	1.48%	0.10%	4.67%	0.30%	92.81%	100.00%	6.44%	1.60%	91.96%	100.00%
	0.66%	0.21%	0.36%	0.70%	0.28%	0.44%	33.74%	3.73%	0.30%	0.71%	32.20%	3.73%
Total	80,279	769,607	1,415,852	50,802	5,685,328	233,709	942,029	9,177,606	7,429,309	770,329	977,968	9,177,606
	0.87%	8.39%	15.43%	0.55%	61.95%	2.55%	10.26%	100.00%	80.95%	8.39%	10.66%	100.00%
	0.87%	8.39%	15.43%	0.55%	61.95%	2.55%	10.26%	100.00%	80.95%	8.39%	10.66%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

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

Table 11

11C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	1,426	6,160	22,464	16,999	118,059	15,788	180,896	47,049
	0.39%	1.67%	6.07%	4.60%	31.92%	4.27%	48.90%	12.72%
	<i>0.79%</i>	<i>3.41%</i>	<i>12.42%</i>	<i>9.40%</i>	<i>65.26%</i>	<i>8.73%</i>	<i>100.00%</i>	<i>26.01%</i>
	45.30%	49.49%	51.10%	50.16%	48.92%	44.94%	48.90%	50.35%
Male	1,579	6,119	20,917	16,388	121,551	14,053	180,607	45,003
	0.43%	1.65%	5.65%	4.43%	32.86%	3.80%	48.83%	12.17%
	<i>0.87%</i>	<i>3.39%</i>	<i>11.58%</i>	<i>9.07%</i>	<i>67.30%</i>	<i>7.78%</i>	<i>100.00%</i>	<i>24.92%</i>
	50.16%	49.16%	47.58%	48.36%	50.37%	40.00%	48.83%	48.16%
Unknown	143	168	578	501	1,717	5,294	8,401	1,390
	0.039%	0.05%	0.16%	0.14%	0.46%	1.43%	2.27%	0.38%
	<i>1.70%</i>	<i>2.00%</i>	<i>6.88%</i>	<i>5.96%</i>	<i>20.44%</i>	<i>63.02%</i>	<i>100.00%</i>	<i>16.55%</i>
	4.54%	1.35%	1.31%	1.48%	0.71%	15.07%	2.27%	1.49%
Total	3,148	12,447	43,959	33,888	241,327	35,135	369,904	93,442
	0.85%	3.36%	11.88%	9.16%	65.24%	9.50%	100.00%	25.26%
	<i>0.85%</i>	<i>3.36%</i>	<i>11.88%</i>	<i>9.16%</i>	<i>65.24%</i>	<i>9.50%</i>	<i>100.00%</i>	<i>25.26%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

493

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

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

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

Table 12. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

12A. 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

12B. 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%	7.88%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
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 12

Number of Protocols with Enrollment Data:

375

12C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
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%
	<i>0.32%</i>	<i>2.30%</i>	<i>9.00%</i>	<i>6.24%</i>	<i>73.17%</i>	<i>8.96%</i>	<i>100.00%</i>	<i>17.87%</i>
	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%
	<i>0.30%</i>	<i>2.17%</i>	<i>8.54%</i>	<i>6.82%</i>	<i>74.42%</i>	<i>7.75%</i>	<i>100.00%</i>	<i>17.83%</i>
	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%
	<i>0.00%</i>	<i>3.39%</i>	<i>1.04%</i>	<i>0.52%</i>	<i>45.43%</i>	<i>49.61%</i>	<i>100.00%</i>	<i>4.96%</i>
	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%
	<i>0.31%</i>	<i>2.24%</i>	<i>8.75%</i>	<i>6.52%</i>	<i>73.75%</i>	<i>8.44%</i>	<i>100.00%</i>	<i>17.82%</i>
	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 13. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2007: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

	Total of Phase III Clinical Trials*	Domestic				Foreign			
		Extra-mural	%	Intra-mural	%	Extra-mural	%	Intra-mural	%
13A. PROTOCOLS REPORTED									
Protocols reporting female only	121	111	91.7%	4	3.3%	5	4.1%	1	0.8%
%	16.2%	16.8%		11.8%		10.0%		25.0%	
Protocols reporting male only	41	40	97.6%	0	0.0%	1	2.4%	0	0.0%
%	5.5%	6.1%		0.0%		2.0%		0.0%	
Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)	491	426	86.8%	28	5.7%	34	6.9%	3	0.6%
%	65.6%	64.4%		82.4%		68.0%		75.0%	
Total Number of Protocols with Enrollment	653	577	88.4%	32	4.9%	40	6.1%	4	0.6%
%	87.2%	87%		94.1%		80.0%		100.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.	96	84	87.5%	2	2.1%	10	10.4%	0	0.0%
%	12.8%	12.7%		5.9%		20.0%		0.0%	
Total Number of Phase III Protocols	749	661	88.3%	34	4.5%	50	6.7%	4	0.5%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

See Table 13A comments on next page.

	Total of Phase III Clinical Trials*	Domestic				Foreign			
		Extra-mural	%	Intra-mural	%	Extra-mural	%	Intra-mural	%
13B. ENROLLMENT REPORTED									
Protocols reporting female only	181,625	144,902	79.8%	7	0.0%	29,707	16.4%	7,009	3.9%
%	30.7%	36.7%		0.0%		19.4%		70.3%	
Protocols reporting male only	79,434	76,650	96.5%	0	0.0%	2,784	3.5%	0	0.0%
%	13.4%	19.4%		0.0%		1.8%		0.0%	
Protocols excluding female-only and men-only enrollment protocols	330,100	173,384	52.5%	33,497	10.1%	120,260	36.4%	2,959	0.9%
%	55.8%	43.9%		100.0%		78.7%		29.7%	
Total Subjects Enrolled	591,159	394,936	66.8%	33,504	5.67%	152,751	25.84%	9,968	1.7%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

See Table 13B comments on next page.

	Total of Phase III Clinical Trials*	Domestic				Foreign			
		Extra-mural	%	Intra-mural	%	Extra-mural	%	Intra-mural	%
13C. MINORITY ENROLLMENT REPORTED**									
Minority Total for all Phase III studies	244,932	83,634	34.1%	4,705	1.9%	149,424	61.0%	7,169	2.9%
%	41.4%	21.2%		14.0%		97.8%		71.9%	

See Table 13C comments on next page.

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

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

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

COMMENTS

Table 13. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported in FY 2007: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign

Table 13A: Total Number of Protocols with Enrollment

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

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

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

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

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

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

Table 13B Total Enrollment Reported

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

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

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

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

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

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

Table 13C Minority Enrollment Reported

Total Minority Enrollment: 41% of Total Enrollment (244,932/591,159)

Total Domestic Minority Enrollment: 36%% of Minority Enrollment (88,339/244,932).

Total Foreign Minority Enrollment: 63%% of Minority Enrollment (156,593/244,932).

Total Domestic Minority Enrollment (Extramural + Intramural): 15% of Total Enrollment (88,339/591,159)

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

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

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

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

14A. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	301,735	134,342		44.52%
%	55.10%	57.64%		
Males	229,062	97,934		42.75%
%	41.83%	42.02%		
Unknown	16,830	794		4.72%
%	3.07%	0.34%		
TOTAL	547,627	233,070	42.56%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	585
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14B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 399			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	5,069	22,153	45,059	263	64,693	1,822	55,182	194,241	125,448	47,629	21,164	194,241
	1.41%	6.15%	12.51%	0.07%	17.96%	0.51%	15.32%	53.91%	34.82%	13.22%	5.87%	53.91%
	2.61%	11.40%	23.20%	0.14%	33.31%	0.94%	28.41%	100.00%	64.58%	24.52%	10.90%	100.00%
	54.34%	46.98%	53.88%	54.45%	52.36%	49.70%	59.67%	53.91%	51.37%	74.34%	40.66%	53.91%
Male	4,213	24,969	38,165	218	58,552	1,772	21,366	149,255	117,914	16,176	15,165	149,255
	1.17%	6.93%	10.59%	0.06%	16.25%	0.49%	5.93%	41.42%	32.73%	4.49%	4.21%	41.42%
	2.82%	16.73%	25.57%	0.15%	39.23%	1.19%	14.32%	100.00%	79.00%	10.84%	10.16%	100.00%
	45.17%	52.95%	45.64%	45.13%	47.39%	48.34%	23.10%	41.42%	48.29%	25.25%	29.14%	41.42%
Unknown	46	35	405	2	319	72	15,930	16,809	825	267	15,717	16,809
	0.01%	0.01%	0.11%	0.00%	0.09%	0.02%	4.42%	4.67%	0.23%	0.07%	4.36%	4.67%
	0.27%	0.21%	2.41%	0.01%	1.90%	0.43%	94.77%	100.00%	4.91%	1.59%	93.50%	100.00%
	0.49%	0.07%	0.48%	0.41%	0.26%	1.96%	17.23%	4.67%	0.34%	0.42%	30.20%	4.67%
Total	9,328	47,157	83,629	483	123,564	3,666	92,478	360,305	244,187	64,072	52,046	360,305
	2.59%	13.09%	23.21%	0.13%	34.29%	1.02%	25.67%	100.00%	67.77%	17.78%	14.44%	100.00%
	2.59%	13.09%	23.21%	0.13%	34.29%	1.02%	25.67%	100.00%	67.77%	17.78%	14.44%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

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

Table 14

14C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
	415	2,190	10,067	3,967	88,698	2,157	107,494	16,639
	0.22%	1.17%	5.37%	2.12%	47.35%	1.15%	57.38%	8.88%
	<i>0.39%</i>	<i>2.04%</i>	<i>9.37%</i>	<i>3.69%</i>	<i>82.51%</i>	<i>2.01%</i>	<i>100.00%</i>	<i>15.48%</i>
	57.24%	62.64%	50.83%	44.99%	59.01%	51.80%	57.38%	50.66%
Male	310	1,306	9,736	4,851	61,601	2,003	79,807	16,203
	0.17%	0.70%	5.20%	2.59%	32.89%	1.07%	42.60%	8.65%
	<i>0.39%</i>	<i>1.64%</i>	<i>12.20%</i>	<i>6.08%</i>	<i>77.19%</i>	<i>2.51%</i>	<i>100.00%</i>	<i>20.30%</i>
	42.76%	37.36%	49.16%	55.01%	40.98%	48.10%	42.60%	49.33%
Unknown	0	0	1	0	16	4	21	1
	0.000%	0.00%	0.00%	0.00%	0.01%	0.00%	0.01%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>4.76%</i>	<i>0.00%</i>	<i>76.19%</i>	<i>19.05%</i>	<i>100.00%</i>	<i>4.76%</i>
	0.00%	0.00%	0.01%	0.00%	0.01%	0.10%	0.01%	0.00%
Total	725	3,496	19,804	8,818	150,315	4,164	187,322	32,843
	0.39%	1.87%	10.57%	4.71%	80.24%	2.22%	100.00%	17.53%
	<i>0.39%</i>	<i>1.87%</i>	<i>10.57%</i>	<i>4.71%</i>	<i>80.24%</i>	<i>2.22%</i>	<i>100.00%</i>	<i>17.53%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

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

Race

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

Ethnicity

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

Table 15. 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

	Total of Phase III Clinical Trials*	Domestic				Foreign			
		Extra-mural	%	Intra-mural	%	Extra-mural	%	Intra-mural	%
15A. PROTOCOLS REPORTED									
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%	

See Table 15A comments on next page.

	Total of Phase III Clinical Trials*	Domestic				Foreign			
		Extra-mural	%	Intra-mural	%	Extra-mural	%	Intra-mural	%
15B. ENROLLMENT REPORTED									
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%	

See Table 15B comments on next page.

	Total of Phase III Clinical Trials*	Domestic				Foreign			
		Extra-mural	%	Intra-mural	%	Extra-mural	%	Intra-mural	%
15C. MINORITY ENROLLMENT REPORTED**									
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%	

See Table 15C comments on next page.

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

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

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

COMMENTS

Table 15. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported in FY 2008: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign

Table 15A: Total Number of Protocols

1. Female Only: There were 126 protocols reporting females only, representing 19.7% (126/639) of protocols with enrollment, and 17.1% of the Total Number of Protocols.

96% were Extramural projects (121); 4% were NIH intramural projects (5)

91% were Domestic protocols (115); 9% were Foreign protocols (11).

2. Male Only: There were 42 protocols reporting males only, representing 6.6% (42/639) of protocols with enrollment, and 5.7% of Total Number of Protocols.

100% were Extramural projects (42); 0% were NIH intramural projects (0).

95% were Domestic protocols (40); 5% were Foreign protocols (2).

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 471 protocols reporting both males and females representing 64% of the total number of protocols.

93% were Extramural projects (439); 7% were NIH intramural projects (32).

91% were Domestic protocols (430); 9% were Foreign protocols (41).

Table 15B: Total Enrollment Reported

1. In Female Only Protocols: There were approximately 219,673 females, representing 27.7% of total enrollment.

96.6% (212,198) were in Extramural projects; 3.4% (7,475) were in NIH intramural projects.

90.8% (199,380) were in Domestic protocols; 9.2% (20,193) were in Foreign protocols.

2. In Male Only Protocols: There were approximately 79,613 males, representing 10.0% of total enrollment.

99.8% (79,454) were in Extramural projects; 0.2% (159) were in NIH intramural projects.

96.1% (76,537) were in Domestic protocols; 3.9% (3,076) were in Foreign protocols.

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were approximately 493,292 subjects, representing 62.2% of total enrollment.

98.2% (484,382) were in Extramural projects; 1.8% (8,910) were in NIH intramural projects.

63.9% (315,188) were in Domestic protocols; 36.1% (178,104) were in Foreign protocols.

Table 15C Minority Enrollment Reported

1. Total Minority Enrollment was 38.9% (308,433) of Total Enrollment (792,578).

Total Minority enrollment, *Extramural* projects (299,057) was 37.7% of Total Enrollment (792,578) and 97.0% of Total Minority Enrollment (308,433).

Total Minority enrollment, *Intramural* projects (9,376), was 1.2% of Total Enrollment (792,578) and 3.0% of Total Minority Enrollment (308,433).

2. Total Minority Enrollment, Domestic only (119,582), was 20.2% of total Domestic Enrollment (591,105) and 38.8% of Total Minority Enrollment (308,433).

3. Total Minority Enrollment, Foreign only (188,851), was 93.7% of total Foreign Enrollment (201,473) and 61.2% of Total Minority Enrollment (308,433).

Table 16. Aggregate Enrollment Data for Extramural Phase III 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	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

16B. 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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
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 16

16C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
	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%
	<i>0.41%</i>	<i>2.14%</i>	<i>8.41%</i>	<i>3.53%</i>	<i>83.87%</i>	<i>1.65%</i>	<i>100.00%</i>	<i>14.49%</i>
	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%
	<i>0.35%</i>	<i>1.50%</i>	<i>12.50%</i>	<i>5.68%</i>	<i>77.64%</i>	<i>2.32%</i>	<i>100.00%</i>	<i>20.04%</i>
	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
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>5.00%</i>	<i>0.00%</i>	<i>40.00%</i>	<i>55.00%</i>	<i>100.00%</i>	<i>5.00%</i>
	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%
	<i>0.39%</i>	<i>1.95%</i>	<i>9.63%</i>	<i>4.17%</i>	<i>82.01%</i>	<i>1.85%</i>	<i>100.00%</i>	<i>16.14%</i>
	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 17. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

17A. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	1,499,945	395,722		26.38%
%	43.39%	48.34%		
Males	1,915,898	421,306		21.99%
%	55.42%	51.47%		
Unknown	41,333	1,518		3.67%
%	1.20%	0.19%		
TOTAL	3,457,176	818,546	23.68%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 1,552

17B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 1,103			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	10,730	124,260	55,037	3,467	716,439	9,823	65,286	985,042	888,411	56,223	40,408	985,042
	0.44%	5.09%	2.26%	0.14%	29.37%	0.40%	2.68%	40.38%	36.41%	2.30%	1.66%	40.38%
	1.09%	12.61%	5.59%	0.35%	72.73%	1.00%	6.63%	100.00%	90.19%	5.71%	4.10%	100.00%
	49.30%	66.48%	23.21%	86.39%	42.04%	71.83%	23.99%	40.38%	42.59%	54.98%	16.07%	40.38%
Male	11,014	61,936	182,077	546	984,999	3,084	169,715	1,413,371	1,194,236	46,009	173,126	1,413,371
	0.45%	2.54%	7.46%	0.02%	40.37%	0.13%	6.96%	57.93%	48.95%	1.89%	7.10%	57.93%
	0.78%	4.38%	12.88%	0.04%	69.69%	0.22%	12.01%	100.00%	84.50%	3.26%	12.25%	100.00%
	50.60%	33.14%	76.78%	13.61%	57.80%	22.55%	62.36%	57.93%	57.25%	45.00%	68.84%	57.93%
Unknown	22	706	15	0	2,595	769	37,169	41,276	3289	20	37,967	41,276
	0.00%	0.03%	0.00%	0.00%	0.11%	0.03%	1.62%	1.69%	0.13%	0.00%	1.56%	1.69%
	0.05%	1.71%	0.04%	0.00%	6.29%	1.86%	90.05%	100.00%	7.97%	0.05%	91.98%	100.00%
	0.10%	0.38%	0.01%	0.00%	0.15%	5.62%	13.66%	1.69%	0.16%	0.02%	15.10%	1.69%
Total	21,766	186,902	237,129	4,013	1,704,033	13,676	272,170	2,439,689	2,085,936	102,252	251,501	2,439,689
	0.89%	7.66%	9.72%	0.16%	69.85%	0.56%	11.16%	100.00%	85.50%	4.19%	10.31%	100.00%
	0.89%	7.66%	9.72%	0.16%	69.85%	0.56%	11.16%	100.00%	85.50%	4.19%	10.31%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

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

Table 17

17C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	876	19,092	96,523	23,152	369,148	6,112	514,903	139,643
	0.09%	1.88%	9.49%	2.28%	36.28%	0.60%	50.61%	13.72%
	<i>0.17%</i>	<i>3.71%</i>	<i>18.75%</i>	<i>4.50%</i>	<i>71.69%</i>	<i>1.19%</i>	<i>100.00%</i>	<i>27.12%</i>
	0.00%	51.47%	53.92%	52.74%	49.59%	53.85%	50.61%	53.36%
Male	822	17,999	82,489	20,743	375,273	5,201	502,527	122,053
	0.08%	1.77%	8.11%	2.04%	36.88%	0.51%	49.39%	12.00%
	<i>0.16%</i>	<i>3.58%</i>	<i>16.41%</i>	<i>4.13%</i>	<i>74.68%</i>	<i>1.03%</i>	<i>100.00%</i>	<i>24.29%</i>
	0.00%	48.53%	46.08%	47.25%	50.41%	45.83%	49.39%	46.64%
Unknown	0	0	1	1	19	36	57	2
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>1.75%</i>	<i>1.75%</i>	<i>33.33%</i>	<i>63.16%</i>	<i>100.00%</i>	<i>3.51%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.32%	0.01%	0.00%
Total	1,698	37,091	179,013	43,896	744,440	11,349	1,017,487	261,698
	0.17%	3.65%	17.59%	4.31%	73.16%	1.12%	100.00%	25.72%
	<i>0.17%</i>	<i>3.65%</i>	<i>17.59%</i>	<i>4.31%</i>	<i>73.16%</i>	<i>1.12%</i>	<i>100.00%</i>	<i>25.72%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

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

Race

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

Ethnicity

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

Table 18. Aggregate Enrollment Data for Intramural 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	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

18B. 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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
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 18

18C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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%
	<i>0.15%</i>	<i>3.51%</i>	<i>31.15%</i>	<i>4.22%</i>	<i>59.50%</i>	<i>1.48%</i>	<i>100.00%</i>	<i>39.03%</i>
	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%
	<i>0.15%</i>	<i>3.24%</i>	<i>29.50%</i>	<i>3.80%</i>	<i>62.02%</i>	<i>1.29%</i>	<i>100.00%</i>	<i>36.69%</i>
	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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>21.74%</i>	<i>78.26%</i>	<i>100.00%</i>	<i>0.00%</i>
	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%
	<i>0.15%</i>	<i>3.38%</i>	<i>30.34%</i>	<i>4.02%</i>	<i>60.73%</i>	<i>1.39%</i>	<i>100.00%</i>	<i>37.87%</i>
	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 19. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2006 and Reported in FY2007: Percent Analysis

19A. SUMMARY TOTALS: Old Form + New Form			
Sex /Gender	Total Enrollment	Minority Enrollment	% Minority by Sex
Females	22,959	9,212	40.12%
%	52.81%	77.58%	
Males	20,511	2,662	12.98%
%	47.18%	22.42%	
Unknown	2	0	0.00%
%	0.00%	0.00%	
TOTAL	43,472	11,874	27.31%
Total %	100%	100.00%	

Total Number of Protocols with Enrollment Data:

36

19B. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 25			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	11	95	544	72	5,366	266	8,523	14,877	6,016	7,307	1,554	14,877
	0.05%	0.45%	2.57%	0.34%	25.31%	1.25%	40.21%	70.18%	28.38%	34.47%	7.33%	70.18%
	0.07%	0.64%	3.66%	0.48%	36.07%	1.79%	57.29%	100.00%	40.44%	49.12%	10.45%	100.00%
	47.83%	45.89%	64.84%	100.00%	56.86%	55.53%	84.06%	70.18%	57.27%	96.78%	49.46%	70.18%
Male	12	112	295	0	4,072	213	1,614	6,318	4,489	243	1,586	6,318
	0.06%	0.53%	1.39%	0.00%	19.21%	1.00%	7.61%	29.81%	21.18%	1.15%	7.48%	29.81%
	0.19%	1.77%	4.67%	0.00%	64.45%	3.37%	25.55%	100.00%	71.05%	3.85%	25.10%	100.00%
	52.17%	54.11%	35.16%	0.00%	43.14%	44.47%	15.92%	29.81%	42.73%	3.22%	50.48%	29.81%
Unknown	0	0	0	0	0	0	2	2	0	0	2	2
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.01%	0.01%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.02%	0.01%	0.00%	0.00%	0.06%	0.01%
Total	23	207	839	72	9,438	479	10,139	21,197	10,505	7,550	3,142	21,197
	0.11%	0.98%	3.96%	0.34%	44.53%	2.26%	47.83%	100.00%	49.56%	35.62%	14.82%	100.00%
	0.11%	0.98%	3.96%	0.34%	44.53%	2.26%	47.83%	100.00%	49.56%	35.62%	14.82%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

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

Table 19

19C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
	6	169	570	174	7,132	31	8,082	919
	0.03%	0.76%	2.56%	0.78%	32.02%	0.14%	36.28%	4.13%
	<i>0.07%</i>	<i>2.09%</i>	<i>7.05%</i>	<i>2.15%</i>	<i>88.25%</i>	<i>0.38%</i>	<i>100.00%</i>	<i>11.37%</i>
	0.00%	37.81%	33.18%	33.79%	36.62%	32.63%	36.28%	33.96%
Male	20	278	1,148	341	12,342	64	14,193	1,787
	0.09%	1.25%	5.15%	1.53%	55.41%	0.29%	63.72%	8.02%
	<i>0.14%</i>	<i>1.96%</i>	<i>8.09%</i>	<i>2.40%</i>	<i>86.96%</i>	<i>0.45%</i>	<i>100.00%</i>	<i>12.59%</i>
	0.00%	62.19%	66.82%	66.21%	63.38%	67.37%	63.72%	66.04%
Unknown	0	0	0	0	0	0	0	0
	0.000%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	26	447	1,718	515	19,474	95	22,275	2,706
	0.12%	2.01%	7.71%	2.31%	87.43%	0.43%	100.00%	12.15%
	<i>0.12%</i>	<i>2.01%</i>	<i>7.71%</i>	<i>2.31%</i>	<i>87.43%</i>	<i>0.43%</i>	<i>100.00%</i>	<i>12.15%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

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

Race

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

Ethnicity

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

Table 20. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

20A. 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

20B. 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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
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 20

20C. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
	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%
	<i>0.17%</i>	<i>1.99%</i>	<i>10.48%</i>	<i>2.34%</i>	<i>84.59%</i>	<i>0.43%</i>	<i>100.00%</i>	<i>14.98%</i>
	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%
	<i>0.15%</i>	<i>1.99%</i>	<i>11.72%</i>	<i>2.33%</i>	<i>83.17%</i>	<i>0.63%</i>	<i>100.00%</i>	<i>16.20%</i>
	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
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>
	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%
	<i>0.16%</i>	<i>1.99%</i>	<i>11.27%</i>	<i>2.34%</i>	<i>83.68%</i>	<i>0.56%</i>	<i>100.00%</i>	<i>15.76%</i>
	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 21. NIH Fourteen Year Trends for Protocol and Enrollment Data: 1995-2008*

21A Part I. Fourteen Year Increases in Protocols and Enrollment Data				
FY Reported	1995		2008	Relative Increase, 2007 / 1995
Total Protocols with Enrollment	3,188		11,045	3.5
Total Enrollment	1,021,493		15,412,355	15.1
Total Minorities	374,433		4,386,636	11.7
% of Minority	36.7%		28.5%	0.8

21A Part II. Seven Year Increases in Protocols and Enrollment Data: Foreign and Domestic				
FY Reported	2002		2008	Relative Increase, 2007 / 1995
Total DOMESTIC Enrollment data	10,192,401		14,134,627	1.4
Total FOREIGN Enrollment	946,083		1,277,728	1.4

Table 21A Comments:

1. There was a 3.5 fold increase in protocols with enrollment reported from 1995 to 2008, from 3,188 protocols to 11,045 protocols.
2. There was a 15.1 fold increase in enrollment reported from 1995 to 2008, from approximately 1M to 15M.
3. There was a 11.7 fold increase in minority enrollment from 1995 to 2008, from approximately 0.4 M to 4M.
4. Domestic and Foreign data were reported for FY 2002-2008, and showed 1.4 fold increase in domestic enrollment (from 10.2M to 14.12M) and a 1.4 fold increase in foreign enrollment (from 0.95M to 1.3M).

*NOTE: Trend data varies over time because the data for each year represent the net total of data resulting from (1) studies continuing from the prior year; (2) the addition of new studies reported and (3) the subtraction of studies that are no longer reported.
 NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

21B. Fourteen Year Summary of Total Number of Protocols Reported: FY 1995-2008

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%	

Total Protocols by Year Reported

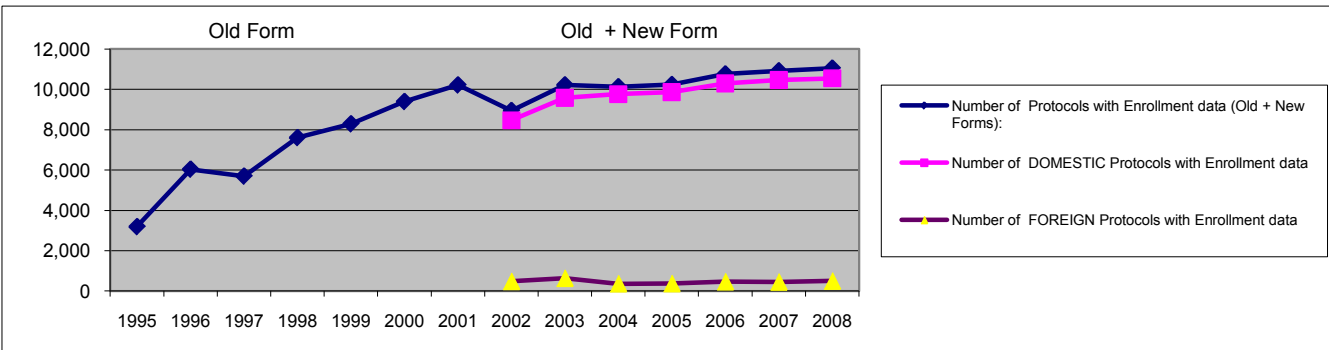


Table 21B Comments:

1. Table 21B and 21B Graph provide the number of OLD and NEW protocols year by year (1995-2008) and the distribution between domestic and foreign protocols for years 2002-2008.
2. The total number of protocols reported with enrollment have leveled off between 10,000 and 11,000 over the last 4 years.
3. The vast majority of protocols were for domestic studies for 2002-2008, ranging from 93.8% to 96.4% of protocols.

* Data have been reported using a combined race/ethnicity format (OLD FORM) since 1995. New protocols began reporting separate race and ethnicity data in FY2002 (NEW FORM). During 2002-2008, data have been reported using both Old and New Forms.

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

21C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2008

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%

Percent Comparison of Domestic and Foreign Enrollment

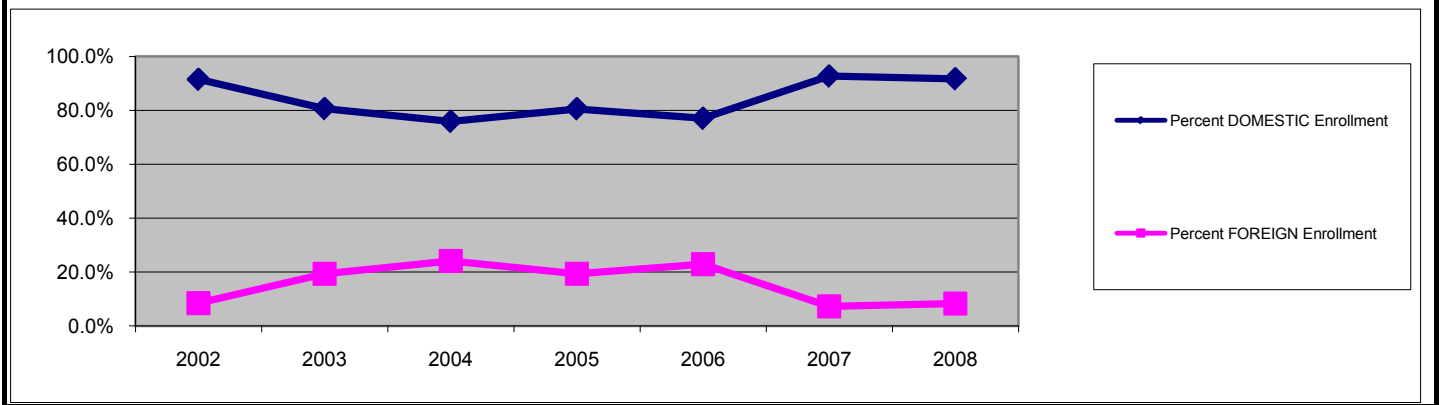


Table 21C Comments:

1. Overall total enrollment has increased, as well as total domestic and foreign enrollment during the last seven years. The percentage of foreign enrollment has decreased from 23.0% in FY2006 to approximately 8.3% in FY 2008 as domestic enrollment incr

Table 22: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported: FY2002-2008: Enrollment Using U.S. Race/Ethnicity Categories

22A . SEVEN YEAR SUMMARY TOTALS: DOMESTIC SUBJECTS IN DOMESTIC PROTOCOLS (Old + New Forms)											
FY Reported	FY Funded		Females		Males		Unknown		Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	2001		6,583,087		3,506,787		59,995		10,149,869	2,754,820	8,425
	%		64.9%		34.6%		0.6%		100.0%	27.1%	
2003	2002		7,392,404		4,393,496		125,457		11,911,357	2,935,363	9,578
	%		62.1%		36.9%		1.1%		100.0%	24.6%	
2004	2003		8,881,299		5,199,765		278,729		14,359,793	3,464,356	9,760
	%		61.8%		36.2%		1.9%		100.0%	24.1%	
2005	2004		7,887,209		4,515,242		267,407		12,669,858	3,468,864	9,862
	%		62.3%		35.6%		2.1%		100.0%	27.4%	
2006	2005		7,684,453		3,566,577		174,671		11,425,701	3,301,135	10,294
	%		67.3%		31.2%		1.5%		100.0%	28.9%	
2007	2006		9,397,957		6,389,817		392,814		16,180,588	4,283,738	10,463
	%		58.1%		39.5%		2.4%		100.0%	26.5%	
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%	

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

Table 22A Comments

1. There were approximately an average of 62.4% females, 36.1% males and 1.5% of unknown sex enrolled in domestic from 2002-2008.
2. There were approximately an average of 26.1% domestic minority subjects enrolled in domestic protocols from 2002-2008.
3. Total domestic enrollment ranged from 10.1M to 16.2M during the past 7 years.
4. The number of domestic protocols increased from 8,425 to 10,548 in 7 years

NOTE on FY2002 Reported Data:

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

NOTE on FY2003 Reported Data:

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

NOTE on FY2004 Reported Data:

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

NOTE on FY2005 Reported Data:

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

NOTE on FY2006 Reported Data:

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

NOTE of FY2007 Reported Data:

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

Table 22: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research

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 22A.

22B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined												
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		1,381
	%	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%		

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													
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)	Total of All Subjects by Ethnicity			
									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%

22D. 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	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%		

* These totals must agree
 ** These totals must agree

Table 23: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2008:Enrollment Using U.S. Race/Ethnicity Categories

23A . Phase III SEVEN YEAR SUMMARY TOTALS: DOMESTIC SUBJECTS IN DOMESTIC PROTOCOLS (Old + New Forms)											
FY Reported	FY Funded		Females		Males		Unknown		Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	2001		264,517		179,179		740		444,436	92,961	582
	%		59.5%		40.3%		0.2%		100.0%	20.9%	
2003	2002		266,913		218,166		1,778		486,857	109,376	643
	%		54.8%		44.8%		0.4%		100.0%	22.5%	
2004	2003		277,333		217,890		1,018		496,241	125,813	549
	%		55.9%		43.9%		0.2%		100.0%	25.4%	
2005	2004		261,589		174,137		2,176		437,902	109,910	517
	%		59.7%		39.8%		0.5%		100.0%	25.1%	
2006	2005		258,467		137,621		4,209		400,297	83,034	564
	%		64.6%		34.4%		1.1%		100.0%	20.7%	
2007	2006		228,289		183,878		16,273		428,440	88,339	609
	%		53.3%		42.9%		3.8%		100.0%	20.6%	
2008	2007		347,982		226,266		16,857		591,105	119,582	585
	%		58.9%		38.3%		2.9%		100.0%	20.2%	

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

Table 23A Comments:

1. There were approximately an average of 58.1% females, 40.6% males and 1.3% of unknown sex enrolled in Phase III domestic protocols from 2002-2008.
2. There were approximately an average of 22.2% domestic minority subjects enrolled in domestic Phase III protocols from 2002-2008.
3. Total domestic Phase III enrollment ranged from 400,297 to 591,105 during these 7 years.
4. The number of domestic Phase III protocols ranged from 517 to 643 between Fiscal Years 2002 and 2008.

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 23A.

Table 23: DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2008:Enrollment Using U.S. Race/Ethnicity Categories

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%		

23C. 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													
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)	Total of All Subjects by Ethnicity			
										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	361,557
	%	0.6%	1.7%	7.1%	0.2%	76.4%	3.3%	10.6%	100.0%	80.0%	11.6%	8.4%	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	44,165		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	44,115		423	
	%	1.2%	0.5%	1.7%	0.3%	53.0%	12.8%	30.5%	100.0%	22.7%			

* These totals must agree
 ** These totals must agree

Table 24. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2008: Enrollment Using U.S. Race/Ethnicity Categories

24A. SEVEN YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)										
FY Reported	FY Funded	Females	Males	Unknown	Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):			
2002	2001	553,056	379,294	13,833	946,083	777,461	482			
	%	58.5%	40.1%	1.5%	100.0%	82.2%				
2003	2002	1,122,077	1,728,000	10,820	2,860,897	2,452,329	638			
	%	39.2%	60.4%	0.4%	100.0%	85.7%				
2004	2003	2,007,798	2,542,127	14,202	4,564,127	4,147,255	365			
	%	44.0%	55.7%	0.3%	100.0%	90.9%				
2005	2004	1,616,713	1,426,665	9,516	3,052,894	2,776,565	371			
	%	53.0%	46.7%	0.3%	100.0%	90.9%				
2006	2005	1,788,820	1,605,628	10,781	3,405,229	3,087,181	464			
	%	52.5%	47.2%	0.3%	100.0%	90.7%				
2007	2006	754,633	497,976	15,261	1,267,870	932,686	451			
	%	59.5%	39.3%	1.2%	100.0%	73.6%				
2008	2007	729,198	540,115	8,415	1,277,728	864,945	497			
	%	57.1%	42.3%	0.7%	100.0%	67.7%				

Table 24AComments:

1. The percent females varied from 39.2% to 59.5% in foreign protocols from 2002-2008; the percent males varied from 39.3% to 60.4%.
2. The percent foreign subjects enrolled using OMB racial/ethnic categories in foreign protocols varied from 73.6% to 90.9% from 2002 to 2008.
3. Total foreign enrollment ranged from 946,083 to 4,564,127 during the past 7 years.
4. The number of foreign protocols ranged from 365 to 638 during the past 7 years

NOTE on FY2002 Reported Data:

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

NOTE on FY2003 Reported Data:

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

NOTE on FY2004 Reported Data:

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

NOTE on FY2005 Reported Data:

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

NOTE on FY2006 Reported Data:

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

NOTE on FY2007 Reported Data:

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

Table 24. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research

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 24A.

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%		

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													
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)	Total of All Subjects by Ethnicity			
										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%

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%		

* These totals must agree
 ** These totals must agree

Table 25. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2008: Enrollment Using U.S. Race/Ethnicity Categories

25A. Part A. Phase III SEVEN YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)										
FY Reported	FY Funded							Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):
		Females	Males	Unknown						
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	54			
	%	53.4%	46.4%	0.2%	100.0%	93.7%				

Table 25A Comments:

1. The percent females varied from 47.4% to 59.2% in Phase III foreign protocols from 2002-2008; the percent males varied from 40.4% to 52.5%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in Phase III foreign protocols increased from 60.4% to 93.7% from 2002 to 2008.
3. Total Phase III foreign enrollment increased from 30,311 to 201,473 during these 7 years.
4. The number of Phase III foreign protocols ranged from 24 to 209 between the years 2002 and 2008.

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 25A.

Table 25. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2008: Enrollment Using U.S. Race/Ethnicity Categories

25B. OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format													
FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other		Total Foreign Enrollment (Old Form)	FOREIGN Subtotal Using US Minority Categories (shaded): OLD FORM			Number of Foreign Protocols with Enrollment data (Old Form):
2002	2001	59	12,269	2,807	1,724	9,579	1,558		27,996	16,859			166
	%	0.2%	43.8%	10.0%	6.2%	34.2%	5.6%		100.0%	60.2%			
2003	2002	77	12,428	280	3,499	15,054	8,077		39,415	16,284			188
	%	0.2%	31.5%	0.7%	8.9%	38.2%	20.5%		100.0%	41.3%			
2004	2003	1	12,068	52	1,007	3,093	7,603		23,824	13,128			10
	%	0.0%	50.7%	0.2%	4.2%	13.0%	31.9%		100.0%	55.1%			
2005	2004	0	12,252	1	1,183	2,257	14		15,707	13,436			5
	%	0.0%	78.0%	0.0%	7.5%	14.4%	0.1%		100.0%	85.5%			
2006	2005	16	12,295	30	12	4,533	675		17,561	12,353			8
	%	0.1%	70.0%	0.2%	0.1%	25.8%	3.8%		100.0%	70.3%			
2007	2006	0	2	1	2	1,662	5		1,672	5			1
	%	0.0%	0.1%	0.1%	0.1%	99.4%	0.3%		100.0%	0.3%			
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%			

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

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%	67.3%	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%	66.3%	18.8%	4.2%	81.5%
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%

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

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	188,777			50
	%	56.1%	0.0%	0.0%	0.0%	0.6%	1.3%	42.0%	100.0%	95.2%			

* These totals must agree
 ** These totals must agree

APPENDICES

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Appendix A

Historical Narrative on the Implementation of the NIH Inclusion Policy

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

Historical Background

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

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

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

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

Revised inclusion guidelines developed in response to this law were published in the *Federal Register*² in March 1994, and they became effective in September 1994. The result was that NIH could not and would not fund any grant, cooperative agreement or contract or support any intramural project to be conducted or funded in Fiscal Year 1995 and thereafter which did not comply with this policy. NIH administrative procedures allow consideration of applications through a peer-review system. During initial peer review, the Scientific Review Group (SRG) evaluates the proposed enrollment of each project involving human subjects and determines whether the plan to include women and minority subjects is scientifically acceptable. The implementation plan determines that an application may be unacceptable if it: 1) fails to provide sufficient information about target enrollment; 2) does not adequately justify limited or lack of

inclusion of women or minorities; or 3) does not realistically address recruitment and retention. For NIH-defined Phase III clinical trials, the Scientific Review Group (SRG) also evaluates the description of plans to conduct analyses, as appropriate, to address differences in the intervention effect by sex/gender and/or racial/ethnic groups. Applications with unacceptable inclusion plans receive an unacceptable gender or minority code, resulting in a bar-to-funding. Such clinical research studies cannot be funded until NIH staff is assured of compliance from the investigators. This may involve changes related to study design. Sometimes applicants are able to remedy the deficiencies found during initial review by providing additional information about the intended enrollment demographics. Research awards covered by this policy require the grantee to report annually on enrollment of women and men, and on the race and ethnicity of research participants so that accrual can be monitored. Annual progress reports submitted by the grantee contain information on research progress which includes research participant enrollment, retention, and when available, preliminary and/or final analyses including analyses by sex/gender and race/ethnicity.

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

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

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

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

Continuing Implementation and Monitoring Activities: 2000 to the Present

Following a Congressional request for an assessment of NIH's progress in implementing the 1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled *Women's Health - NIH Has Increased Its Efforts to Include Women in Research*.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 than 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.

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8. LaRosa, J. H., Seto, B., Caban, C.E., Hayunga, E.G., Including Women and Minorities in Clinical Research, *Applied Clinical Trials*, Vol. 4, No.5, p. 31-38, 1995.
9. McCarthy, C.R., Historical Background of Clinical Trials Involving Women and Minorities, *Academic Medicine*, Vol. 69, No.9, p. 695-698, 1994.
10. Pinn, V.W., The Role of the NIH's Office of Research on Women's Health, *Academic Medicine*, Vol. 69, No. 9, p. 698-702, 1994.
11. Gallin, J, (2002). Principles and Practices of Clinical Research: Chapter 11 NIH Policy on the Inclusion of Women and Minorities as Subjects of Clinical Research, Academic Press, San Diego, California, pp 146-157.

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

NIH Office of Extramural Research Inclusion of Women and Minorities Policy Implementation Website:

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

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

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

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

Appendix B

Explanation of Sex and Minority Codes

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

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

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

Appendix C

NIH Tracking and Inclusion Committee Members

- Full Committee

<p style="text-align: center;">NIH Tracking and Inclusion Committee 2007-2008 List of Members</p>

Office of the Director

Office of Research on Women's Health

Vivian Pinn (Co-Chair), Angela Bates, Janine Smith

Office of Extramural Research

Robin Wagner*, Israel Lederhendler, Katrina Pearson, Maria Koshy, Svetlana Diggs,
Lakshmi Kompella

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*, Michelle Johnson, 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,

National Institute of Neurological Disorders and Stroke

Lynn Morin*, Kristy Woolbert, Aricia Ajose

National Institute of Nursing Research

Paul Cotton*, Angela Marshall

National Library of Medicine

Hua-Chuan Sim*, Valerie Florence

Warren G. Magnuson Clinical Center

Kim Jarema*, 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 superseded by the [Target/Planned Enrollment Table](#) and [Inclusion Enrollment Reports](#) that use the 1997 OMB 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: 301-496-6014 Fax: 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:

Robin A. Barr, D. Phil.

National Institute on Aging

Gateway Building, Room 2C218

7201 Wisconsin Avenue, MSC 9205

Bethesda, MD 20892-9205 (20814 for courier service)

Telephone: 301-496-9322

Email: BarrR@mail.nih.gov

Howard B. Moss, M.D.

National Institute on Alcohol Abuse and Alcoholism

5635 Fishers Lane #3097

Bethesda, MD 20892-9304 (20852 for courier service)

Telephone: 301.402.0944

Email: mossh@mail.nih.gov

Anna Ramsey-Ewing, Ph.D.

National Institute of Allergy and Infectious Diseases

6700B Rockledge Drive

Room 2144

Bethesda, MD 20892

Telephone: 301-435-8536

Email: arewing@mail.nih.gov

Madeline Turkeltaub, Ph.D.
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Blvd. Suite 800
Bethesda, MD. 20892
Telephone: 301-594-5058
Email: Mturkeltaub@mail.nih.gov

Anthony Demsey, Ph.D.
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Blvd.
Suite 200, Rm. 241
Bethesda, MD 20892
Telephone: (301)402-7039
Email: demseya@mail.nih.gov

Paulette S. Gray, Ph.D.
National Cancer Institute
6116 Executive Blvd., Room 8001
Bethesda, MD 20892
Telephone: 301/496-5147
Email: grayp@mail.nih.gov

Eugene Hayunga, Ph.D.
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 2C01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 435-6856
Email: hayungae@mail.nih.gov

Castilla F. McNamara, Ph.D., M.P.A.
National Institute on Deafness and Other Communication Disorders
EPS 400B, 6120 Executive Blvd.,
Rockville, MD 20852
Telephone: 301 402-0909
Email: McNamara@mail.nih.gov

Norman S. Braveman, Ph.D.
National Institute of Dental and Craniofacial Research
Building 31, Room 5B55
Bethesda, MD 20852
Telephone: (301) 594-2089
Email: Norman.Braveman@nih.gov

Brent Stanfield, Ph.D.
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Blvd, Room 715
Bethesda, MD 20892-5456
Telephone: 301-594-8843
Email: stanfibr@mail.nih.gov

Teresa Levitin, Ph.D.
National Institute on Drug Abuse,
6101 Executive Boulevard, Rm. 220, MSC 8401
Bethesda, Maryland 20892-8401
Telephone: (301) 443-2755
Email: tlevitin@mail.nih.gov

Dennis Lang, Ph.D.
National Institute of Environmental Health Sciences,
NIH P.O. Box 12233, MD EC20
Research Triangle Park, NC 27709
Telephone: 919-541-7729
Email: lang4@mail.nih.gov

Paivi H. Miskala, M.S.P.H., Ph.D.
National Eye Institute
5635 Fishers Lane, Suite 1300, MSC 9300
Bethesda, MD 20892-9300
Telephone 301-451-2020
Email miskalap@mail.nih.gov

Alison Cole, Ph.D.
National Institute of General Medical Sciences
Natcher Building
Building 45, Room 2AS49K
Bethesda, MD 20892-6200
Telephone: (301) 594-3827
Email: coleal@mail.nih.gov

Stephen C. Mockrin, Ph.D.
National Heart, Lung, and Blood Institute
6701 Rockledge Drive MSC 7922
Bethesda, MD 20892-7922 (20817 for courier service)
Telephone: 301 435-0260
Email: mockrins@mail.nih.gov

Bettie J. Graham, Ph.D.
National Human Genome Research Institute
Suite 4076 MSC 9305
5635 Fishers Lane
National Institutes of Health
Bethesda, MD 20892-9305 (20852 for courier service)
Telephone: 301-496-7531
EMail: grahambyj@mail.nih.gov

Sherman Ragland
National Institute of Mental Health
Neuroscience Building
6001 Executive Boulevard, Room 8128
Bethesda, MD 20852
Telephone: (301)443-2847
Email: ragland@mail.nih.gov

Frances Yee, Ph.D.
National Institute of Neurological Disorders and Stroke
6001 Executive Boulevard, Room 2227, MSC 9520
Bethesda, MD 20892- 9525
Telephone: 301-496-9135
Email: yeef@mail.nih.gov

Barbara A. Smothers, Ph.D.
National Institute of Nursing Research
6701 Democracy Blvd., Suite 710
Bethesda MD 20892-4870
Telephone: 301-594-5976
EMail: bsmother@mail.nih.gov

Valerie Florance, Ph.D.
National Library of Medicine
Rockledge 1, Suite 301
6705 Rockledge Drive, Bethesda, MD 20892
Telephone: 301.594.4882
Email: floranv@mail.nih.gov

April I. Bower RN, MS
National Center for Complementary and Alternative Medicine
6707 Democracy Blvd., Suite 401
Bethesda MD 20892 USA
Telephone: 301-451-3560
Email: bowera@mail.nih.gov

Derrick C. Tabor, Ph.D.,
National Center on Minority Health and Health Disparities
6707 Democracy Blvd., Suite 800
Bethesda, MD 20892-5465
Telephone: (301) 402-1366
Email: tabord@mail.nih.gov

Shelia McClure, Ph.D.
National Center for Research Resources
6701 Democracy Blvd., Rm 932
Bethesda, MD 20892
Telephone: (301) 451-6536
Email: mcclurSh@mail.nih.gov

Barbara Sina, Ph.D.
Fogarty International Center
Building 31 Room B2C39
Bethesda, MD 20892-2220
Telephone: (301) 402-9467
Email: sinab@mail.nih.gov

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 Table 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:

Robin A. Barr, D. Phil.

National Institute on Aging

Gateway Building, Room 2C218
7201 Wisconsin Avenue, MSC 9205
Bethesda, MD 20892-9205 (20814 for courier service)
Telephone: 301-496-9322
Email: BarrR@mail.nih.gov

Howard B. Moss, M.D.

National Institute on Alcohol Abuse and Alcoholism

5635 Fishers Lane #3097
Bethesda, MD 20892-9304 (20852 for courier service)
Telephone: 301.402.0944
Email: mossh@mail.nih.gov

Anna Ramsey-Ewing, Ph.D.

National Institute of Allergy and Infectious Diseases

6700B Rockledge Drive
Room 2144
Bethesda, MD 20892
Telephone: 301-435-8536
Email: arewing@mail.nih.gov

Madeline Turkeltaub, Ph.D.

National Institute of Arthritis and Musculoskeletal and Skin Diseases

6701 Democracy Blvd. Suite 800
Bethesda, MD. 20892
Telephone: 301-594-5058
Email: Mturkeltaub@mail.nih.gov

Anthony Demsey, Ph.D.

National Institute of Biomedical Imaging and Bioengineering

6707 Democracy Blvd.
Suite 200, Rm. 241
Bethesda, MD 20892
Telephone: (301)402-7039
Email: demseya@mail.nih.gov

Paulette S. Gray, Ph.D.

National Cancer Institute

6116 Executive Blvd., Room 8001
Bethesda, MD 20892

Telephone: 301/496-5147
Email: grayp@mail.nih.gov

Eugene Hayunga, Ph.D.
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 2C01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 435-6856
Email: hayungae@mail.nih.gov

Castilla F. McNamara, Ph.D., M.P.A.
National Institute on Deafness and Other Communication Disorders
EPS 400B, 6120 Executive Blvd.,
Rockville, MD 20852
Telephone: 301 402-0909
Email: McNamara@mail.nih.gov

Norman S. Braveman, Ph.D.
National Institute of Dental and Craniofacial Research
Building 31, Room 5B55
Bethesda, MD 20852
Telephone: (301) 594-2089
Email: Norman.Braveman@nih.gov

Brent Stanfield, Ph.D.
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Blvd, Room 715
Bethesda, MD 20892-5456
Telephone: 301-594-8843
Email: stanfibr@mail.nih.gov

Teresa Levitin, Ph.D.
National Institute on Drug Abuse,
6101 Executive Boulevard, Rm. 220, MSC 8401
Bethesda, Maryland 20892-8401
Telephone: (301) 443-2755
Email: tlevitin@mail.nih.gov

Dennis Lang, Ph.D.
National Institute of Environmental Health Sciences,
NIH P.O. Box 12233, MD EC20
Research Triangle Park, NC 27709
Telephone: 919-541-7729
Email: lang4@mail.nih.gov

Paivi H. Miskala, M.S.P.H., Ph.D.

National Eye Institute

5635 Fishers Lane, Suite 1300, MSC 9300

Bethesda, MD 20892-9300

Telephone 301-451-2020

Email miskalap@mail.nih.gov

Alison Cole, Ph.D.

National Institute of General Medical Sciences

Natcher Building

Building 45, Room 2AS49K

Bethesda, MD 20892-6200

Telephone: (301) 594-3827

Email: coleal@mail.nih.gov

Stephen C. Mockrin, Ph.D.

National Heart, Lung, and Blood Institute

6701 Rockledge Drive MSC 7922

Bethesda, MD 20892-7922 (20817 for courier service)

Telephone: 301 435-0260

Email: mockrins@mail.nih.gov

Bettie J. Graham, Ph.D.

National Human Genome Research Institute

Suite 4076 MSC 9305

5635 Fishers Lane

National Institutes of Health

Bethesda, MD 20892-9305 (20852 for courier service)

Telephone: 301-496-7531

EMail: grahambyj@mail.nih.gov

Sherman Ragland

National Institute of Mental Health

Neuroscience Building

6001 Executive Boulevard, Room 8128

Bethesda, MD 20852

Telephone: (301)443-2847

Email: ragland@mail.nih.gov

Frances Yee, Ph.D.

National Institute of Neurological Disorders and Stroke

6001 Executive Boulevard, Room 2227, MSC 9520

Bethesda, MD 20892- 9525

Telephone: 301-496-9135

Email: yeef@mail.nih.gov

Barbara A. Smothers, Ph.D.
National Institute of Nursing Research
6701 Democracy Blvd., Suite 710
Bethesda MD 20892-4870
Telephone: 301-594-5976
EMail: bsmother@mail.nih.gov

Valerie Florance, Ph.D.
National Library of Medicine
Rockledge 1, Suite 301
6705 Rockledge Drive, Bethesda, MD 20892
Telephone: 301.594.4882
Email: floranv@mail.nih.gov

April I. Bower RN, MS
National Center for Complementary and Alternative Medicine
6707 Democracy Blvd., Suite 401
Bethesda MD 20892 USA
Telephone: 301-451-3560
Email: bowera@mail.nih.gov

Derrick C. Tabor, Ph.D.,
National Center on Minority Health and Health Disparities
6707 Democracy Blvd., Suite 800
Bethesda, MD 20892-5465
Telephone: (301) 402-1366
Email: tabord@mail.nih.gov

Shelia McClure, Ph.D.
National Center for Research Resources
6701 Democracy Blvd., Rm 932
Bethesda, MD 20892
Telephone: (301) 451-6536
Email: mcclurSh@mail.nih.gov

Barbara Sina, Ph.D.
Fogarty International Center
Building 31 Room B2C39
Bethesda, MD 20892-2220
Telephone: (301) 402-9467
Email: sinab@mail.nih.gov

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."

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			Total
	Females	Males	Unknown or Not Reported	
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.

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 FY2007 and Reported in FY2008*

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Table 1A. Aggregate Enrollment Data for Extramural and Intramural Research Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	9,243,966	2,609,666		28.23%
%	59.98%	59.15%		
Males	5,991,739	1,784,488		29.78%
%	38.88%	40.45%		
Unknown	176,650	17,952		10.16%
%	1.15%	0.41%		
TOTAL	15,412,355	4,412,106	28.63%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 11,045

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 10,130			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	88,985	784,371	926,927	30,265	5,707,628	111,622	1,185,254	8,835,052	7,086,149	680,974	1,067,930	8,835,053
	0.60%	5.30%	6.27%	0.20%	38.60%	0.75%	8.02%	59.75%	47.92%	4.61%	7.22%	59.75%
	1.01%	8.88%	10.49%	0.34%	64.60%	1.26%	13.42%	100.00%	80.20%	7.71%	12.09%	100.00%
	66.16%	67.15%	50.51%	62.32%	59.14%	61.35%	67.09%	59.75%	59.64%	60.98%	59.74%	59.75%
Male	44,962	381,775	900,247	18,091	3,932,371	68,884	428,310	5,774,640	4,776,382	429,040	569,218	5,774,640
	0.30%	2.58%	6.09%	0.12%	26.60%	0.47%	2.90%	39.05%	32.30%	2.90%	3.85%	39.05%
	0.78%	6.61%	15.59%	0.31%	68.10%	1.19%	7.42%	100.00%	82.71%	7.43%	9.86%	100.00%
	33.43%	32.68%	49.06%	37.25%	40.74%	37.86%	24.25%	39.05%	40.20%	38.42%	31.84%	39.05%
Unknown	547	1,907	7,861	204	11,268	1,435	153,022	176,244	19,113	6,685	150,446	176,244
	0.00%	0.01%	0.05%	0.00%	0.08%	0.01%	1.03%	1.19%	0.13%	0.05%	1.02%	1.19%
	0.31%	1.08%	4.46%	0.12%	6.39%	0.81%	86.82%	100.00%	10.84%	3.79%	85.36%	100.00%
	0.41%	0.16%	0.43%	0.42%	0.12%	0.79%	8.66%	1.19%	0.16%	0.60%	8.42%	1.19%
Total	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
	0.91%	7.90%	12.41%	0.33%	65.27%	1.23%	11.95%	100.00%	80.36%	7.55%	12.09%	100.00%
	0.91%	7.90%	12.41%	0.33%	65.27%	1.23%	11.95%	100.00%	80.36%	7.55%	12.09%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female %	18,744	17,235	27,673	1,364	344,984	35,365	235,609	680,974	2,522,763
	1.68%	1.54%	2.48%	0.12%	30.89%	3.17%	21.10%	60.98%	17.06%
	2.75%	2.53%	4.06%	0.20%	50.66%	5.19%	34.60%	100.00%	28.55%
	54.59%	54.51%	32.35%	57.58%	66.49%	54.43%	62.16%	60.98%	59.14%
Male %	15,412	14,265	57,615	968	173,063	29,500	138,217	429,040	1,725,239
	1.38%	1.28%	5.16%	0.09%	15.50%	2.64%	12.38%	38.42%	11.67%
	3.59%	3.32%	13.43%	0.23%	40.34%	6.88%	32.22%	100.00%	29.88%
	44.89%	45.12%	67.35%	40.86%	33.36%	45.40%	36.47%	38.42%	40.44%
Unknown %	179	116	260	37	778	114	5,201	6,685	17,933
	0.02%	0.01%	0.02%	0.00%	0.07%	0.01%	0.47%	0.60%	0.12%
	2.68%	1.74%	3.89%	0.55%	11.64%	1.71%	77.80%	100.00%	10.18%
	0.52%	0.37%	0.30%	1.56%	0.15%	0.18%	1.37%	0.60%	0.42%
TOTAL	34,335	31,616	85,548	2,369	518,825	64,979	379,027	1,116,699	4,265,935
	3.07%	2.83%	7.66%	0.21%	46.46%	5.82%	33.94%	100.00%	28.85%
	3.07%	2.83%	7.66%	0.21%	46.46%	5.82%	33.94%	100.00%	28.85%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 1A

Number of Protocols with Enrollment Data:

915

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
Female	1,404	10,876	57,384	17,239	310,618	11,393	408,914	86,903
	0.22%	1.74%	9.16%	2.75%	49.59%	1.82%	65.28%	13.87%
	<i>0.34%</i>	<i>2.66%</i>	<i>14.03%</i>	<i>4.22%</i>	<i>75.96%</i>	<i>2.79%</i>	<i>100.00%</i>	<i>21.25%</i>
	72.75%	66.90%	57.87%	59.82%	67.45%	57.79%	65.28%	59.45%
Male	526	5,369	41,776	11,578	149,736	8,114	217,099	59,249
	0.08%	0.86%	6.67%	1.85%	23.90%	1.30%	34.66%	9.46%
	<i>0.24%</i>	<i>2.47%</i>	<i>19.24%</i>	<i>5.33%</i>	<i>68.97%</i>	<i>3.74%</i>	<i>100.00%</i>	<i>27.29%</i>
	27.25%	33.02%	42.13%	40.17%	32.51%	41.16%	34.66%	40.53%
Unknown	0	13	4	2	179	208	406	19
	0.00%	0.00%	0.00%	0.00%	0.03%	0.03%	0.06%	0.00%
	<i>0.00%</i>	<i>3.20%</i>	<i>0.99%</i>	<i>0.49%</i>	<i>44.09%</i>	<i>51.23%</i>	<i>100.00%</i>	<i>4.68%</i>
	0.00%	0.08%	0.00%	0.01%	0.04%	1.06%	0.06%	0.01%
Total	1,930	16,258	99,164	28,819	460,533	19,715	626,419	146,171
	0.31%	2.60%	15.83%	4.60%	73.52%	3.15%	100.00%	23.33%
	<i>0.31%</i>	<i>2.60%</i>	<i>15.83%</i>	<i>4.60%</i>	<i>73.52%</i>	<i>3.15%</i>	<i>100.00%</i>	<i>23.33%</i>
	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 (9,243,966; 59.98%) than males (5,991,739; 38.88%) were enrolled in aggregate extramural and intramural research protocols. More minority females (2,609,666; 59.15%) than minority males (1,784,488; 40.45%) were enrolled in aggregate extramural and intramural research protocols.

Race

Approximately 28.63% (4,412,106) of participants in aggregate extramural and intramural research (15,412,355 total) were classified as U.S. minorities. Largest identified racial group was White at 73.52% following the 1977 OMB standards and 65.27% following the 1997 OMB standards. Largest identified racial minority group was Black or African American at 15.83% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 12.41% 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 0.33%.

Ethnicity

7.55% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. For participants reporting ethnicity as Hispanic/Latino: Largest identified racial group was White at 46.46% (2nd highest category is Unknown/Other at 33.94%) Smallest identified racial group was Hawaiian/Pacific Islander at 0.21%. Of the 1,116,699 participants, 60.98% were women and 38.42% were men. 4.60% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 2A. Aggregate Enrollment Data for Extramural and Intramural Phase III Research Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	455,612	169,540		37.21%
%	57.48%	54.97%		
Males	319,732	137,983		43.16%
%	40.34%	44.74%		
Unknown	17,234	895		5.19%
%	2.17%	0.29%		
TOTAL	792,578	308,418	38.91%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 639

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 475			
	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	7,624	49,144	55,367	413	152,504	6,538	22,062	293,652	245,283	37,180	11,189	293,652
	1.36%	8.78%	9.89%	0.07%	27.23%	1.17%	3.94%	52.43%	43.80%	6.64%	2.00%	52.43%
	2.60%	16.74%	18.85%	0.14%	51.93%	2.23%	7.51%	100.00%	83.53%	12.66%	3.81%	100.00%
	50.81%	51.57%	53.67%	57.68%	54.21%	53.87%	42.13%	52.43%	53.22%	57.78%	32.13%	52.43%
Male	7,329	46,049	47,492	299	127,583	5,474	14,942	249,168	214,030	26,746	8,392	249,168
	1.31%	8.22%	8.48%	0.05%	22.78%	0.98%	2.67%	44.49%	38.22%	4.78%	1.50%	44.49%
	2.94%	18.48%	19.06%	0.12%	51.20%	2.20%	6.00%	100.00%	85.90%	10.73%	3.37%	100.00%
	48.84%	48.32%	46.03%	41.76%	45.35%	45.11%	28.53%	44.49%	46.44%	41.56%	24.10%	44.49%
Unknown	53	103	307	4	1,257	124	15,366	17,214	1,549	425	15,240	17,214
	0.01%	0.02%	0.05%	0.00%	0.22%	0.02%	2.74%	3.07%	0.28%	0.08%	2.72%	3.07%
	0.31%	0.60%	1.78%	0.02%	7.30%	0.72%	89.26%	100.00%	9.00%	2.47%	88.53%	100.00%
	0.35%	0.11%	0.30%	0.56%	0.45%	1.02%	29.34%	3.07%	0.34%	0.66%	43.77%	3.07%
Total	15,006	95,296	103,166	716	281,344	12,136	52,370	560,034	460,862	64,351	34,821	560,034
	2.68%	17.02%	18.42%	0.13%	50.24%	2.17%	9.35%	100.00%	82.29%	11.49%	6.22%	100.00%
	2.68%	17.02%	18.42%	0.13%	50.24%	2.17%	9.35%	100.00%	82.29%	11.49%	6.22%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	6,525	95	336	65	12,568	3,171	14,420	37,180	146,074
	10.14%	0.15%	0.52%	0.10%	19.53%	4.93%	22.41%	57.78%	26.08%
	17.55%	0.26%	0.90%	0.17%	33.80%	8.53%	38.78%	100.00%	49.74%
	49.96%	41.48%	46.86%	53.28%	56.38%	56.08%	64.73%	57.78%	53.92%
Male	6,493	127	373	54	9,614	2,421	7,664	26,746	123,921
	10.09%	0.20%	0.58%	0.08%	14.94%	3.76%	11.91%	41.56%	22.13%
	24.28%	0.47%	1.39%	0.20%	35.95%	9.05%	28.65%	100.00%	49.73%
	49.72%	55.46%	52.02%	44.26%	43.13%	42.82%	34.40%	41.56%	45.75%
Unknown	42	7	8	3	111	62	192	425	894
	0.07%	0.01%	0.01%	0.00%	0.17%	0.10%	0.30%	0.66%	0.16%
	9.88%	1.65%	1.88%	0.71%	26.12%	14.58%	45.18%	100.00%	5.19%
	0.32%	3.06%	1.12%	2.46%	0.50%	1.10%	0.86%	0.66%	0.33%
TOTAL	13,060	229	717	122	22,293	5,654	22,276	64,351	270,889
	20.29%	0.36%	1.11%	0.19%	34.64%	8.79%	34.62%	100.00%	48.37%
	20.29%	0.36%	1.11%	0.19%	34.64%	8.79%	34.62%	100.00%	48.37%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 2A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Protocols with Enrollment Data:
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total		
Female	654	3,472	13,637	5,703	135,843	2,651	161,960	23,466	
	0.28%	1.49%	5.86%	2.45%	58.42%	1.14%	69.65%	10.09%	
	<i>0.40%</i>	<i>2.14%</i>	<i>8.42%</i>	<i>3.52%</i>	<i>83.87%</i>	<i>1.64%</i>	<i>100.00%</i>	<i>14.49%</i>	
	72.67%	76.44%	60.76%	59.15%	71.21%	62.20%	69.65%	62.53%	
Male	246	1,070	8,807	3,939	54,902	1,600	70,564	14,062	
	0.11%	0.46%	3.79%	1.69%	23.61%	0.69%	30.34%	6.05%	
	<i>0.35%</i>	<i>1.52%</i>	<i>12.48%</i>	<i>5.58%</i>	<i>77.80%</i>	<i>2.27%</i>	<i>100.00%</i>	<i>19.93%</i>	
	27.33%	23.56%	39.24%	40.85%	28.78%	37.54%	30.34%	37.47%	
Unknown	0	0	1	0	8	11	20	1	
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	
	<i>0.00%</i>	<i>0.00%</i>	<i>5.00%</i>	<i>0.00%</i>	<i>40.00%</i>	<i>55.00%</i>	<i>100.00%</i>	<i>5.00%</i>	
	0.00%	0.00%	0.00%	0.00%	0.00%	0.26%	0.01%	0.00%	
Total	900	4,542	22,445	9,642	190,753	4,262	232,544	37,529	
	0.39%	1.95%	9.65%	4.15%	82.03%	1.83%	100.00%	16.14%	
	<i>0.39%</i>	<i>1.95%</i>	<i>9.65%</i>	<i>4.15%</i>	<i>82.03%</i>	<i>1.83%</i>	<i>100.00%</i>	<i>16.14%</i>	
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	

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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 (455,612; 57.48%) than males (319,732; 40.34%) were enrolled in aggregate extramural and intramural Phase III research protocols. More minority females (169,540; 54.97%) than minority males (137,983; 44.74%) were enrolled in aggregate extramural and intramural Phase III research protocols.

Race

Approximately 38.91% (308,418) of participants in aggregate extramural and intramural Phase III research (792,578 total) were classified as U.S. minorities. Largest identified racial group was White at 82.03% following the 1977 OMB standards and 50.24% following the 1997 OMB standards. Largest identified racial minority group was Black or African American at 9.65% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 18.42% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.39%. According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.13%.

Ethnicity

11.49% 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 34.64% (2nd largest category is Unknown/Other at 34.62%) Smallest identified racial group was Hawaiian/Pacific Islander at 0.19%. Of the 64,351 participants, 57.78% were women and 41.56% were men. 4.15% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 3A. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. 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
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II. 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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
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%	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 3A

Number of Protocols with Enrollment Data:

375

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
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%
	<i>0.32%</i>	<i>2.30%</i>	<i>9.00%</i>	<i>6.24%</i>	<i>73.17%</i>	<i>8.96%</i>	<i>100.00%</i>	<i>17.87%</i>
	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%
	<i>0.30%</i>	<i>2.17%</i>	<i>8.54%</i>	<i>6.82%</i>	<i>74.42%</i>	<i>7.75%</i>	<i>100.00%</i>	<i>17.83%</i>
	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
	0.00%	0.01%	0.00%	0.00%	0.11%	0.13%	0.25%	0.01%
	<i>0.00%</i>	<i>3.39%</i>	<i>1.04%</i>	<i>0.52%</i>	<i>45.43%</i>	<i>49.61%</i>	<i>100.00%</i>	<i>4.96%</i>
	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%
	<i>0.31%</i>	<i>2.24%</i>	<i>8.75%</i>	<i>6.52%</i>	<i>73.75%</i>	<i>8.44%</i>	<i>100.00%</i>	<i>17.82%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments: [Reference Table 2A](#)

Sex/Gender

Excluding sex-specific studies, the number of males (4,147,836 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 4A. Aggregate Enrollment Data for Extramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	258,878	122,914		47.48%
%	48.98%	49.98%		
Males	252,692	122,137		48.33%
%	47.81%	49.66%		
Unknown	17,007	882		5.19%
%	3.22%	0.36%		
TOTAL	528,577	245,933	46.53%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 440

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 351			
	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	7,373	40,812	48,897	230	120,489	6,259	11,332	235,392	201,598	25,804	7,990	235,392
	1.55%	8.56%	10.26%	0.05%	25.28%	1.31%	2.38%	49.39%	42.30%	5.41%	1.68%	49.39%
	3.13%	17.34%	20.77%	0.10%	51.19%	2.66%	4.81%	100.00%	85.64%	10.06%	3.39%	100.00%
	50.13%	47.41%	52.76%	43.64%	51.94%	54.68%	28.93%	49.39%	51.03%	49.60%	27.04%	49.39%
Male	7,282	45,169	43,486	293	110,244	5,064	12,687	224,225	191,895	25,795	6,535	224,225
	1.53%	9.48%	9.12%	0.06%	23.13%	1.06%	2.66%	47.05%	40.26%	5.41%	1.37%	47.05%
	3.25%	20.14%	19.39%	0.13%	49.17%	2.26%	5.66%	100.00%	85.58%	11.50%	2.91%	100.00%
	49.51%	52.47%	46.92%	55.60%	47.52%	44.24%	32.39%	47.05%	48.58%	49.58%	22.11%	47.05%
Unknown	53	103	294	4	1,257	124	15,152	16,987	1,536	425	15,026	16,987
	0.01%	0.02%	0.06%	0.00%	0.26%	0.03%	3.18%	3.56%	0.32%	0.09%	3.15%	3.56%
	0.31%	0.61%	1.73%	0.02%	7.40%	0.73%	89.20%	100.00%	9.04%	2.50%	88.46%	100.00%
	0.36%	0.12%	0.32%	0.76%	0.54%	1.08%	38.68%	3.56%	0.39%	0.82%	50.85%	3.56%
Total	14,708	86,084	92,677	527	231,990	11,447	39,171	476,604	395,029	52,024	29,551	476,604
	3.09%	18.06%	19.45%	0.11%	48.68%	2.40%	8.22%	100.00%	82.88%	10.92%	6.20%	100.00%
	3.09%	18.06%	19.45%	0.11%	48.68%	2.40%	8.22%	100.00%	82.88%	10.92%	6.20%	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
Female	6639	86	261	52	10,392	3,114	5,260	25,804
	12.76%	0.17%	0.50%	0.10%	19.98%	5.99%	10.11%	49.60%
	25.73%	0.33%	1.01%	0.20%	40.27%	12.07%	20.38%	100.00%
	49.67%	39.45%	41.04%	47.71%	51.76%	58.74%	42.70%	49.60%
Male	6684	125	367	54	9,573	2,125	6,867	25,795
	12.85%	0.24%	0.71%	0.10%	18.40%	4.08%	13.20%	49.58%
	25.91%	0.48%	1.42%	0.21%	37.11%	8.24%	26.62%	100.00%
	50.01%	57.34%	57.70%	49.54%	47.68%	40.09%	55.74%	49.58%
Unknown	42	7	8	3	111	62	192	425
	0.08%	0.01%	0.02%	0.01%	0.21%	0.12%	0.37%	0.82%
	9.88%	1.65%	1.88%	0.71%	26.12%	14.59%	45.18%	100.00%
	0.31%	3.21%	1.26%	2.75%	0.55%	1.17%	1.56%	0.82%
TOTAL	13,365	218	636	109	20,076	5,301	12,319	52,024
	25.69%	0.42%	1.22%	0.21%	38.59%	10.19%	23.68%	100.00%
	25.69%	0.42%	1.22%	0.21%	38.59%	10.19%	23.68%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
119,223
25.02%
50.65%
50.13%
117,734
24.70%
52.51%
49.50%
881
0.18%
5.19%
0.37%
237,838
49.90%
49.90%
100.00%

Table 4A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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	526	2,074	1,007	19,128	667	23,486	3,691
	0.16%	1.01%	3.99%	1.94%	36.80%	1.28%	45.19%	7.10%
	<i>0.36%</i>	<i>2.24%</i>	<i>8.83%</i>	<i>4.29%</i>	<i>81.44%</i>	<i>2.84%</i>	<i>100.00%</i>	<i>15.72%</i>
	46.93%	50.33%	46.24%	42.20%	45.12%	44.80%	45.19%	45.60%
Male	95	519	2,410	1,379	23,253	811	28,467	4,403
	0.18%	1.00%	4.64%	2.65%	44.74%	1.56%	54.77%	8.47%
	<i>0.33%</i>	<i>1.82%</i>	<i>8.47%</i>	<i>4.84%</i>	<i>81.68%</i>	<i>2.85%</i>	<i>100.00%</i>	<i>15.47%</i>
	53.07%	49.67%	53.73%	57.80%	54.86%	54.47%	54.77%	54.39%
Unknown	0	0	1	0	8	11	20	1
	0.000%	0.00%	0.00%	0.00%	0.02%	0.02%	0.04%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>5.00%</i>	<i>0.00%</i>	<i>40.00%</i>	<i>55.00%</i>	<i>100.00%</i>	<i>5.00%</i>
	0.00%	0.00%	0.02%	0.00%	0.02%	0.74%	0.04%	0.01%
Total	179	1,045	4,485	2,386	42,389	1,489	51,973	8,095
	0.34%	2.01%	8.63%	4.59%	81.56%	2.86%	100.00%	15.58%
	<i>0.34%</i>	<i>2.01%</i>	<i>8.63%</i>	<i>4.59%</i>	<i>81.56%</i>	<i>2.86%</i>	<i>100.00%</i>	<i>15.58%</i>
	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 females (258,878 or 48.98%) exceeded the number of males (252,692 or 47.81%) enrolled in Phase III Extramural Research Protocols. Excluding sex-specific studies, the number of minority females (122,914 or 49.98%) exceeded the number of minority males (122,137 or 49.66%) enrolled in Phase III Extramural Research Protocols.

Race

Approximately 46.56% (245,933) of participants in Phase III Extramural Research (528,577 total) were classified as U.S. minorities. Largest identified racial group was White at 81.56% following the 1977 OMB standards. Largest identified racial group was White at 48.68% following the 1997 OMB standards. Largest identified racial minority group was Black or African American at 8.63% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 19.45% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.34%. According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.11%.

Ethnicity

10.92% 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 38.59% (2nd largest category is American Indian/Alaska Native at 25.69%) Smallest identified racial group was Hawaiian/Pacific Islander at 0.21%. Of the 52,024 participants, 49.6% were women and 49.5% were men. 4.59% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 5A. Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	844,881	220,179		26.06%
%	34.72%	37.32%		
Males	1,552,834	369,341		23.78%
%	63.82%	62.60%		
Unknown	35,546	515		1.45%
%	1.46%	0.09%		
TOTAL	2,433,261	590,035	24.25%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 1,506

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 1,124			
	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	9,006	86,705	46,191	3,680	554,980	4,166	40,793	745,521	667,029	35,085	43,407	745,521
	0.40%	3.88%	2.06%	0.16%	24.81%	0.19%	1.82%	33.33%	29.82%	1.57%	1.94%	33.33%
	1.21%	11.63%	6.20%	0.49%	74.44%	0.56%	5.47%	100.00%	89.47%	4.71%	5.82%	100.00%
	45.44%	48.44%	20.02%	86.53%	35.95%	46.30%	16.28%	33.33%	35.14%	42.76%	16.92%	33.33%
Male	10,784	91,874	184,538	573	985,794	4,831	177,507	1,455,901	1,227,524	46,950	181,427	1,455,901
	0.48%	4.11%	8.25%	0.03%	44.07%	0.22%	7.94%	65.08%	54.88%	2.10%	8.11%	65.08%
	0.74%	6.31%	12.68%	0.04%	67.71%	0.33%	12.19%	100.00%	84.31%	3.22%	12.46%	100.00%
	54.41%	51.32%	79.96%	13.47%	63.86%	53.70%	70.86%	65.08%	64.66%	57.22%	70.71%	65.08%
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%	0.13%	0.00%	1.44%	1.59%	0.17%	0.00%	1.42%	1.59%
	0.08%	1.20%	0.14%	0.00%	7.88%	0.00%	90.69%	100.00%	10.61%	0.05%	89.34%	100.00%
	0.15%	0.24%	0.02%	0.00%	0.18%	0.00%	12.86%	1.59%	0.20%	0.02%	12.37%	1.59%
Total	19,820	179,007	230,777	4,253	1,543,574	8,997	250,517	2,236,945	1,898,321	82,052	256,572	2,236,945
	0.89%	8.00%	10.32%	0.19%	69.00%	0.40%	11.20%	100.00%	84.86%	3.67%	11.47%	100.00%
	0.89%	8.00%	10.32%	0.19%	69.00%	0.40%	11.20%	100.00%	84.86%	3.67%	11.47%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	46	15	375	23	23473	3,076	8,077	35,085	181,298
	0.06%	0.02%	0.46%	0.03%	28.61%	3.75%	9.84%	42.76%	8.10%
	0.13%	0.04%	1.07%	0.07%	66.90%	8.77%	23.02%	100.00%	24.32%
	43.40%	36.59%	12.22%	46.94%	43.16%	50.70%	44.07%	42.76%	35.16%
Male	52	26	2694	26	30919	2,991	10,242	46,950	333,761
	0.06%	0.03%	3.28%	0.03%	37.68%	3.65%	12.48%	57.22%	14.92%
	0.11%	0.06%	5.74%	0.06%	65.86%	6.37%	21.81%	100.00%	22.92%
	49.06%	63.41%	87.78%	53.06%	56.84%	49.30%	55.88%	57.22%	64.74%
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%
	7.55%	0.00%	0.00%	0.00%	0.00%	0.00%	0.05%	0.02%	0.10%
TOTAL	106	41	3,069	49	54,392	6,067	18,328	82,052	515,574
	0.13%	0.05%	3.74%	0.06%	66.29%	7.39%	22.34%	100.00%	23.05%
	0.13%	0.05%	3.74%	0.06%	66.29%	7.39%	22.34%	100.00%	23.05%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 5A.

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
Female	150	3,487	31,027	4,217	59,014	1,465	99,360	38,881
	0.08%	1.78%	15.80%	2.15%	30.06%	0.75%	50.61%	19.81%
	<i>0.15%</i>	<i>3.51%</i>	<i>31.23%</i>	<i>4.24%</i>	<i>59.39%</i>	<i>1.47%</i>	<i>100.00%</i>	<i>39.13%</i>
	51.55%	52.55%	52.02%	53.48%	49.54%	53.60%	50.61%	52.22%
Male	141	3,149	28,622	3,668	60,103	1,250	96,933	35,580
	0.07%	1.60%	14.58%	1.87%	30.62%	0.64%	49.38%	18.12%
	<i>0.15%</i>	<i>3.25%</i>	<i>29.53%</i>	<i>3.78%</i>	<i>62.00%</i>	<i>1.29%</i>	<i>100.00%</i>	<i>36.71%</i>
	48.45%	47.45%	47.98%	46.52%	50.45%	45.74%	49.38%	47.78%
Unknown	0	0	0	0	5	18	23	0
	0.000%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>21.74%</i>	<i>78.26%</i>	<i>100.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.66%	0.01%	0.00%
Total	291	6,636	59,649	7,885	119,122	2,733	196,316	74,461
	0.15%	3.38%	30.38%	4.02%	60.68%	1.39%	100.00%	37.93%
	<i>0.15%</i>	<i>3.38%</i>	<i>30.38%</i>	<i>4.02%</i>	<i>60.68%</i>	<i>1.39%</i>	<i>100.00%</i>	<i>37.93%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

382

Legend

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

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

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

Data Table Comments:

Sex/Gender

Excluding sex-specific studies, the number of males (1,552,834 or 63.82%) exceeded the number of females (844,881 or 34.72%) enrolled in Intramural Research Protocols.
 Excluding sex-specific studies, the number of minority males (369,341 or 62.60%) exceeded the number of minority females (220,179 or 37.32%) enrolled in Intramural Research Protocols.

Race

Approximately 24.25% (590,035) of participants in aggregate Intramural Research (2,433,261 total) were classified as U.S. minorities.
 Largest identified racial group was White at 60.68% following the 1977 OMB standards and 69.00% following the 1997 OMB standards.
 Largest identified racial minority group was Black or African American at 30.38% following the 1977 OMB standards.
 Largest identified racial minority group was Black or African American at 10.32% 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 0.19%.

Ethnicity

3.67% 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 66.29% (2nd largest category was Unknown/Other at 22.34%)
 Smallest identified racial group was Asian at 0.05%.
 Of the 82,052 participants, 57.22% were men and 42.76% were women.
 4.02% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 6A. Aggregate Enrollment Data for Intramural Phase III Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	4,054	969		23.90%
%	45.52%	51.82%		
Males	4,624	888		19.20%
%	51.93%	47.49%		
Unknown	227	13		0.00%
%	2.55%	0.70%		
TOTAL	8,905	1,870	21.00%	
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	6	36	624	69	695	2	1,467	2,899	1,356	61	1,482	2,899
	0.10%	0.61%	10.66%	1.18%	11.87%	0.03%	25.06%	49.52%	23.16%	1.04%	25.32%	49.52%
	0.21%	1.24%	21.52%	2.38%	23.97%	0.07%	50.60%	100.00%	46.77%	2.10%	51.12%	100.00%
	85.71%	29.51%	58.87%	100.00%	52.06%	50.00%	45.04%	49.52%	53.83%	46.56%	46.25%	49.52%
Male	1	86	423	0	640	2	1,576	2,728	1,150	70	1,508	2,728
	0.02%	1.47%	7.23%	0.00%	10.93%	0.03%	26.92%	46.60%	19.64%	1.20%	25.76%	46.60%
	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%	39.91%	0.00%	47.94%	50.00%	48.39%	46.60%	45.65%	53.44%	47.07%	46.60%
Unknown	0	0	13	0	0	0	214	227	13	0	214	227
	0.00%	0.00%	0.22%	0.00%	0.00%	0.00%	3.66%	3.88%	0.22%	0.00%	3.66%	3.88%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	1.23%	0.00%	0.00%	0.00%	6.57%	3.88%	0.52%	0.00%	6.68%	3.88%
Total	7	122	1,060	69	1,335	4	3,257	5,854	2,519	131	3,204	5,854
	0.12%	2.08%	18.11%	1.18%	22.80%	0.07%	55.64%	100.00%	43.03%	2.24%	54.73%	100.00%
	0.12%	2.08%	18.11%	1.18%	22.80%	0.07%	55.64%	100.00%	43.03%	2.24%	54.73%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	1	0	0	0	2	1	57	61	796
	0.76%	0.00%	0.00%	0.00%	1.53%	0.76%	43.51%	46.56%	13.60%
	1.64%	0.00%	0.00%	0.00%	3.28%	1.64%	93.44%	100.00%	27.46%
	100.00%	0.00%	0.00%	0.00%	66.67%	100.00%	45.24%	46.56%	57.23%
Male	0	0	0	0	1	0	69	70	582
	0.00%	0.00%	0.00%	0.00%	0.76%	0.00%	52.67%	53.44%	9.94%
	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%	54.76%	53.44%	41.84%
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%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.93%
TOTAL	1	0	0	0	3	1	126	131	1,391
	0.76%	0.00%	0.00%	0.00%	2.29%	0.76%	96.18%	100.00%	23.76%
	0.76%	0.00%	0.00%	0.00%	2.29%	0.76%	96.18%	100.00%	23.76%
	100.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 6A.

Number of Protocols with Enrollment Data:

10

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
Female	2	23	121	27	977	5	1,155	173
	0.07%	0.75%	3.97%	0.88%	32.02%	0.16%	37.86%	5.67%
	<i>0.17%</i>	<i>1.99%</i>	<i>10.48%</i>	<i>2.34%</i>	<i>84.59%</i>	<i>0.43%</i>	<i>100.00%</i>	<i>14.98%</i>
	40.00%	36.51%	35.91%	36.49%	38.25%	27.78%	37.86%	36.12%
Male	3	40	216	47	1,577	13	1,896	306
	0.10%	1.31%	7.08%	1.54%	51.69%	0.43%	62.14%	10.03%
	<i>0.16%</i>	<i>2.11%</i>	<i>11.39%</i>	<i>2.48%</i>	<i>83.18%</i>	<i>0.69%</i>	<i>100.00%</i>	<i>16.14%</i>
	60.00%	63.49%	64.09%	63.51%	61.75%	72.22%	62.14%	63.88%
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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	5	63	337	74	2,554	18	3,051	479
	0.16%	2.06%	11.05%	2.43%	83.71%	0.59%	100.00%	15.70%
	<i>0.16%</i>	<i>2.06%</i>	<i>11.05%</i>	<i>2.43%</i>	<i>83.71%</i>	<i>0.59%</i>	<i>100.00%</i>	<i>15.70%</i>
	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)
<i>Italics:</i>	Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)
Typeface:	Percentage of Total No. of Participants sorted by Race/Ethnicity (Column Total)

Data Table Comments:

Sex/Gender

There were 33 Phase III Intramural Research Protocols of which 3 (8.11%) were female-only protocols and 0 (0.0%) were male-only protocols. Excluding sex-specific studies, the number of males (4,624 or 51.93%) exceeded the number of females (4,054 or 45.52%) enrolled in Phase III Intramural Research Protocols. Excluding sex-specific studies, the number of minority females (969 or 51.82%) exceeded the number of minority males (888 or 47.49%) enrolled in Phase III Intramural Research Protocols.

Race

Approximately 21.00% (1,870) of participants in aggregate Phase III Intramural Research (8,905 total) were classified as U.S. minorities. Largest identified racial group was White at 83.71% following the 1977 OMB standards and Unknown/Other at 55.64% following the 1997 OMB Standards. Largest identified racial minority group was Black or African American at 11.05% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 18.11% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.16%. According to the 1997 OMB standards, the smallest identified racial minority was More than One Race at 0.07%.

Ethnicity

2.24% 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 96.18% (2nd largest category was White at 2.29%) Asian, Black or African American, and Hawaiian/Pacific Islander all reported 0.0%. Of the 131 participants, 46.56% were women and 53.44% were men. 2.43% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

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

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	8,514,768	2,121,057		24.91%
%	60.24%	60.23%		
Males	5,451,624	1,386,456		25.43%
%	38.57%	39.37%		
Unknown	168,235	14,178		8.43%
%	1.19%	0.40%		
TOTAL	14,134,627	3,521,691		24.92%
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 10,548

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 9,639			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	77,294	515,311	797,115	26,842	5,479,338	104,853	1,107,739	8,108,492	6,504,236	583,754	1,020,503	8,108,493
	0.57%	3.81%	5.90%	0.20%	40.55%	0.78%	8.20%	60.01%	48.14%	4.32%	7.55%	60.01%
	0.95%	6.36%	9.83%	0.33%	67.58%	1.29%	13.66%	100.00%	80.22%	7.20%	12.59%	100.00%
	69.22%	71.64%	50.37%	64.25%	59.20%	62.14%	67.87%	60.01%	59.83%	61.73%	60.20%	60.01%
Male	33,962	202,857	779,208	14,734	3,768,101	62,493	374,597	5,235,952	4,351,840	356,748	527,364	5,235,952
	0.25%	1.50%	5.77%	0.11%	27.89%	0.46%	2.77%	38.75%	32.21%	2.64%	3.90%	38.75%
	0.65%	3.87%	14.88%	0.28%	71.97%	1.19%	7.15%	100.00%	83.11%	6.81%	10.07%	100.00%
	30.41%	28.20%	49.24%	35.27%	40.71%	37.03%	22.95%	38.75%	40.03%	37.73%	31.11%	38.75%
Unknown	412	1,119	6,293	204	8,602	1,404	149,795	167,829	15,542	5,101	147,186	167,829
	0.00%	0.01%	0.05%	0.00%	0.06%	0.01%	1.11%	1.24%	0.12%	0.04%	1.09%	1.24%
	0.25%	0.67%	3.75%	0.12%	5.13%	0.84%	89.25%	100.00%	9.26%	3.04%	87.70%	100.00%
	0.37%	0.16%	0.40%	0.49%	0.09%	0.83%	9.18%	1.24%	0.14%	0.54%	8.68%	1.24%
Total	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
	0.83%	5.32%	11.71%	0.31%	68.50%	1.25%	12.08%	100.00%	80.46%	7.00%	12.54%	100.00%
	0.83%	5.32%	11.71%	0.31%	68.50%	1.25%	12.08%	100.00%	80.46%	7.00%	12.54%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	8,741	4,973	26,953	1,357	317,552	28,539	195,639	583,754	2,034,606
	0.92%	0.53%	2.85%	0.14%	33.58%	3.02%	20.69%	61.73%	15.06%
	1.50%	0.85%	4.62%	0.23%	54.40%	4.89%	33.51%	100.00%	25.09%
	60.17%	70.18%	32.00%	57.48%	67.83%	55.29%	61.60%	61.73%	59.67%
Male	5,728	1,997	57,002	967	149,853	22,973	118,228	356,748	1,361,335
	0.61%	0.21%	6.03%	0.10%	15.85%	2.43%	12.50%	37.73%	10.07%
	1.61%	0.56%	15.98%	0.27%	42.01%	6.44%	33.14%	100.00%	26.00%
	39.43%	28.18%	67.69%	40.96%	32.01%	44.51%	37.22%	37.73%	39.92%
Unknown	59	116	260	37	771	106	3,752	5,101	13,955
	0.01%	0.01%	0.03%	0.00%	0.08%	0.01%	0.40%	0.54%	0.10%
	1.16%	2.27%	5.10%	0.73%	15.11%	2.08%	73.55%	100.00%	8.32%
	0.41%	1.64%	0.31%	1.57%	0.16%	0.21%	1.18%	0.54%	0.41%
TOTAL	14,528	7,086	84,215	2,361	468,176	51,618	317,619	945,603	3,409,896
	1.54%	0.75%	8.91%	0.25%	49.51%	5.46%	33.59%	100.00%	25.24%
	1.54%	0.75%	8.91%	0.25%	49.51%	5.46%	33.59%	100.00%	25.24%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 7A

Number of Protocols with Enrollment Data:

909

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	1,389	10,840	57,371	16,851	308,521	11,304	406,276	86,451
	0.22%	1.74%	9.22%	2.71%	49.57%	1.82%	65.28%	13.89%
	<i>0.34%</i>	<i>2.67%</i>	<i>14.12%</i>	<i>4.15%</i>	<i>75.94%</i>	<i>2.78%</i>	<i>100.00%</i>	<i>21.28%</i>
	0.00%	95.37%	91.42%	66.95%	88.07%	7.05%	65.28%	77.33%
Male	11,114	526	5,369	8,112	41,775	148,776	215,672	25,121
	1.79%	0.08%	0.86%	1.30%	6.71%	23.91%	34.65%	4.04%
	<i>5.15%</i>	<i>0.24%</i>	<i>2.49%</i>	<i>3.76%</i>	<i>19.37%</i>	<i>68.98%</i>	<i>100.00%</i>	<i>11.65%</i>
	0.00%	4.63%	8.56%	32.23%	11.93%	92.83%	34.65%	22.47%
Unknown	2	0	13	208	4	179	406	223
	0.000%	0.00%	0.00%	0.03%	0.00%	0.03%	0.07%	0.04%
	<i>0.49%</i>	<i>0.00%</i>	<i>3.20%</i>	<i>51.23%</i>	<i>0.99%</i>	<i>44.09%</i>	<i>100.00%</i>	<i>54.93%</i>
	0.00%	0.00%	0.02%	0.83%	0.00%	0.11%	0.07%	0.20%
Total	12,505	11,366	62,753	25,171	350,300	160,259	622,354	111,795
	2.01%	1.83%	10.08%	4.04%	56.29%	25.75%	100.00%	17.96%
	<i>2.01%</i>	<i>1.83%</i>	<i>10.08%</i>	<i>4.04%</i>	<i>56.29%</i>	<i>25.75%</i>	<i>100.00%</i>	<i>17.96%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	0.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

More females (8,523,500 or 60.24%) than males (5,456,883 or 38.57%) were enrolled in aggregate Domestic Extramural and Intramural Research Protocols. More minority females (2,121,057 or 60.23%) than males (1,386,456 or 39.37%) were enrolled in aggregate Domestic Extramural and Intramural Research Protocols.

Race

Approximately 24.92% (3,521,691) of participants in aggregate Domestic Extramural and Intramural Research (14,148,669 total) were classified as U.S. minorities. Largest identified racial group was White at 56.29% following the 1977 OMB standards and White at 68.43% following the 1997 OMB standards. Largest identified racial minority group was Black or African American at 10.08% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 11.70% following the 1997 OMB standards. According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.31%. According to the 1977 OMB standards, the smallest identified racial minority was Asian/Pacific Islander at 1.83%.

Ethnicity

6.99% 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 49.51% (2nd largest category was Unknown/Other at 33.59%). Smallest identified racial group was Hawaiian/Pacific Islander at 0.25%. Of the 945,603 participants, 61.73% were women and 37.73% were men. 4.04% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 8A. DOMESTIC Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	7,618,658	1,946,882		25.55%
%	64.58%	62.96%		
Males	4,043,042	1,131,742		27.99%
%	34.27%	36.60%		
Unknown	135,905	13,841		10.18%
%	1.15%	0.45%		
TOTAL	11,797,605	3,092,465	26.21%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 8,971

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 8,475			
	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	67,661	496,935	738,323	22,853	4,832,239	96,418	1,058,786	7,313,215	5,785,475	547,576	980,165	7,313,216
	0.59%	4.37%	6.49%	0.20%	42.49%	0.85%	9.31%	64.30%	50.87%	4.81%	8.62%	64.30%
	0.93%	6.80%	10.10%	0.31%	66.08%	1.32%	14.48%	100.00%	79.11%	7.49%	13.40%	100.00%
	74.17%	72.78%	55.01%	61.41%	62.97%	60.88%	76.27%	64.30%	63.96%	63.15%	67.10%	64.30%
Male	23,176	184,775	597,572	14,156	2,833,163	60,557	211,447	3,924,846	3,245,753	314,393	364,700	3,924,846
	0.20%	1.62%	5.25%	0.12%	24.91%	0.53%	1.86%	34.51%	28.54%	2.76%	3.21%	34.51%
	0.59%	4.71%	15.23%	0.36%	72.19%	1.54%	5.39%	100.00%	82.70%	8.01%	9.29%	100.00%
	25.41%	27.06%	44.52%	38.04%	36.92%	38.24%	15.23%	34.51%	35.88%	36.26%	24.97%	34.51%
Unknown	382	1,084	6,243	204	8,176	1,404	118,029	135,522	14,543	5,083	115,896	135,522
	0.00%	0.01%	0.05%	0.00%	0.07%	0.01%	1.04%	1.19%	0.13%	0.04%	1.02%	1.19%
	0.28%	0.80%	4.61%	0.15%	6.03%	1.04%	87.09%	100.00%	10.73%	3.75%	85.52%	100.00%
	0.42%	0.16%	0.47%	0.55%	0.11%	0.89%	8.50%	1.19%	0.16%	0.59%	7.93%	1.19%
Total	91,219	682,794	1,342,138	37,213	7,673,578	158,379	1,388,262	11,373,583	9,045,771	867,052	1,460,761	11,373,584
	0.80%	6.00%	11.80%	0.33%	67.47%	1.39%	12.21%	100.00%	79.53%	7.62%	12.84%	100.00%
	0.80%	6.00%	11.80%	0.33%	67.47%	1.39%	12.21%	100.00%	79.53%	7.62%	12.84%	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
Female	8661	4952	26642	1360	290680	28386	186895	547,576
	1.00%	0.57%	3.07%	0.16%	33.53%	3.27%	21.56%	63.15%
	1.58%	0.90%	4.87%	0.25%	53.08%	5.18%	34.13%	100.00%
	59.95%	70.09%	32.78%	58.17%	70.74%	55.27%	62.37%	63.15%
Male	5,728	1,997	54383	941	1,194,399	22,870	109,035	314,393
	0.66%	0.23%	6.27%	0.11%	13.78%	2.64%	12.58%	36.26%
	1.82%	0.64%	17.30%	0.30%	37.99%	7.27%	34.68%	100.00%
	39.65%	28.27%	66.90%	40.25%	29.07%	44.53%	36.39%	36.26%
Unknown	59	116	260	37	771	106	3,734	5,083
	0.01%	0.01%	0.03%	0.00%	0.09%	0.01%	0.43%	0.59%
	1.16%	2.28%	5.12%	0.73%	15.17%	2.09%	73.46%	100.00%
	0.41%	1.64%	0.32%	1.58%	0.19%	0.21%	1.25%	0.59%
TOTAL	14,448	7,065	81,285	2,338	4,108,900	51,362	299,664	867,052
	1.67%	0.81%	9.37%	0.27%	47.39%	5.92%	34.56%	100.00%
	1.67%	0.81%	9.37%	0.27%	47.39%	5.92%	34.56%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B

1,899,765
16.70%
25.98%
62.86%

1,108,710
9.75%
28.25%
36.68%

13,822
0.12%
10.20%
0.46%

3,022,297
26.57%
26.57%
100.00%

Table 8A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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	1,228	7,294	26,006	12,589	248,516	9,810	305,443	47,117
	0.29%	1.72%	6.13%	2.97%	58.61%	2.31%	72.03%	11.11%
	<i>0.40%</i>	<i>2.39%</i>	<i>8.51%</i>	<i>4.12%</i>	<i>81.36%</i>	<i>3.21%</i>	<i>100.00%</i>	<i>15.43%</i>
	76.27%	76.92%	66.53%	63.00%	73.74%	58.26%	72.03%	67.15%
Male	382	2,176	13,082	7,392	88,326	6,838	118,196	23,032
	0.09%	0.51%	3.09%	1.74%	20.83%	1.61%	27.87%	5.43%
	<i>0.32%</i>	<i>1.84%</i>	<i>11.07%</i>	<i>6.25%</i>	<i>74.73%</i>	<i>5.79%</i>	<i>100.00%</i>	<i>19.49%</i>
	23.73%	22.95%	33.46%	36.99%	26.21%	40.61%	27.87%	32.82%
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%
	<i>0.00%</i>	<i>3.39%</i>	<i>1.04%</i>	<i>0.52%</i>	<i>45.43%</i>	<i>49.67%</i>	<i>100.00%</i>	<i>4.96%</i>
	0.00%	0.14%	0.01%	0.01%	0.05%	1.13%	0.09%	0.03%
Total	1,610	9,483	39,092	19,983	337,016	16,838	424,022	70,168
	0.38%	2.24%	9.22%	4.71%	79.48%	3.97%	100.00%	16.55%
	<i>0.38%</i>	<i>2.24%</i>	<i>9.22%</i>	<i>4.71%</i>	<i>79.48%</i>	<i>3.97%</i>	<i>100.00%</i>	<i>16.55%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

496

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 (7,618,658 or 64.58%) than males (4,043,042 or 34.27%) were enrolled in aggregate Domestic Extramural Research Protocols. More minority females (1,946,882 or 62.96%) than males (1,131,742 or 36.60%) were enrolled in aggregate Domestic Extramural Research Protocols.

Race

Approximately 26.21% (3,092,465) of participants in aggregate Domestic Extramural Research (11,797,605 total) were classified as U.S. minorities. Largest identified racial group was White at 79.48% following the 1977 OMB standards and 67.47% following the 1997 OMB standards. Largest identified racial minority group was Black or African American at 9.22% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 11.80% following the 1997 OMB standards. According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.33%. According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.38%.

Ethnicity

7.62% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. For participants reporting ethnicity as Hispanic/Latino: Largest identified racial group was White at 47.39% (2nd largest category was Unknown/Other at 34.56%). Smallest identified racial group was Hawaiian/Pacific Islander at 0.27%. Of the 867,052 participants, 63.15% were women and 36.26% were men. 4.71% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 9A. DOMESTIC Aggregate Enrollment Data for Intramural Research Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	895,404	172,273		19.24%
%	38.31%	37.50%		
Males	1,409,288	286,978		20.36%
%	60.30%	62.47%		
Unknown	32,330	109		0.34%
%	1.38%	0.02%		
TOTAL	2,337,022	459,360	19.66%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 1,577

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 1,164			
	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	10,519	18,206	56,951	3,983	642,897	8,291	53,866	794,713	714,141	35,740	44,832	794,713
	0.49%	0.85%	2.66%	0.19%	30.05%	0.39%	2.52%	37.15%	33.39%	1.67%	2.10%	37.15%
	1.32%	2.29%	7.17%	0.50%	80.90%	1.04%	6.78%	100.00%	89.86%	4.50%	5.64%	100.00%
	49.30%	50.26%	23.95%	87.42%	40.81%	81.63%	21.22%	37.15%	39.29%	45.86%	18.42%	37.15%
Male	10,786	17,984	180,807	573	931,848	1,866	168,222	1,312,086	1,102,691	42,170	167,225	1,312,086
	0.50%	0.84%	8.45%	0.03%	43.56%	0.09%	7.86%	61.34%	51.55%	1.97%	7.82%	61.34%
	0.82%	1.37%	13.78%	0.04%	71.02%	0.14%	12.82%	100.00%	84.04%	3.21%	12.74%	100.00%
	50.56%	49.65%	76.04%	12.58%	59.16%	18.37%	66.26%	61.34%	60.66%	54.11%	68.71%	61.34%
Unknown	30	35	35	0	422	0	31,785	32,307	984	17	31,306	32,307
	0.00%	0.00%	0.00%	0.00%	0.02%	0.00%	1.49%	1.51%	0.05%	0.00%	1.46%	1.51%
	0.09%	0.11%	0.11%	0.00%	1.31%	0.00%	98.38%	100.00%	3.05%	0.05%	96.90%	100.00%
	0.14%	0.10%	0.01%	0.00%	0.03%	0.00%	12.52%	1.51%	0.05%	0.02%	12.86%	1.51%
Total	21,335	36,225	237,793	4,556	1,575,167	10,157	253,873	2,139,106	1,817,816	77,927	243,363	2,139,106
	1.00%	1.69%	11.12%	0.21%	73.64%	0.47%	11.87%	100.00%	84.98%	3.64%	11.38%	100.00%
	1.00%	1.69%	11.12%	0.21%	73.64%	0.47%	11.87%	100.00%	84.98%	3.64%	11.38%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	82	22	342	49	27,137	217	7,891	35,740	132,978
	0.11%	0.03%	0.44%	0.06%	34.82%	0.28%	10.13%	45.86%	6.22%
	0.23%	0.06%	0.96%	0.14%	75.93%	0.61%	22.08%	100.00%	16.73%
	57.75%	45.83%	11.47%	65.33%	47.09%	62.90%	47.23%	45.86%	34.59%
Male	52	26	2639	26	30,490	128	8,809	42,170	251,315
	0.07%	0.03%	3.39%	0.03%	39.13%	0.16%	11.30%	54.11%	11.75%
	0.12%	0.06%	6.26%	0.06%	72.30%	0.30%	20.89%	100.00%	19.15%
	36.62%	54.17%	88.53%	34.67%	52.91%	37.10%	52.72%	54.11%	65.38%
Unknown	8	0	0	0	0	0	9	17	109
	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.02%	0.01%
	47.06%	0.00%	0.00%	0.00%	0.00%	0.00%	52.94%	100.00%	0.34%
	5.63%	0.00%	0.00%	0.00%	0.00%	0.00%	0.05%	0.02%	0.03%
TOTAL	142	48	2,981	75	57,627	345	16,709	77,927	384,402
	0.18%	0.06%	3.83%	0.10%	73.95%	0.44%	21.44%	100.00%	17.97%
	0.18%	0.06%	3.83%	0.10%	73.95%	0.44%	21.44%	100.00%	17.97%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 9A

Number of Protocols with Enrollment Data:

413

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
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%
	<i>0.15%</i>	<i>3.51%</i>	<i>31.15%</i>	<i>4.22%</i>	<i>59.50%</i>	<i>1.48%</i>	<i>100.00%</i>	<i>39.03%</i>
	51.55%	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%
	<i>0.15%</i>	<i>3.24%</i>	<i>29.50%</i>	<i>3.80%</i>	<i>62.02%</i>	<i>1.29%</i>	<i>100.00%</i>	<i>36.69%</i>
	48.45%	47.15%	47.76%	46.50%	50.16%	45.41%	49.11%	47.58%
Unknown	0	0	0	0	5	18	23	0
	0.000%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>21.74%</i>	<i>78.26%</i>	<i>100.00%</i>	<i>0.00%</i>
	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	2,739	197,916	74,958
	0.15%	3.38%	30.34%	4.02%	60.73%	1.39%	100.00%	37.87%
	<i>0.15%</i>	<i>3.38%</i>	<i>30.34%</i>	<i>4.02%</i>	<i>60.73%</i>	<i>1.39%</i>	<i>100.00%</i>	<i>37.87%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Data Table Comments:

Sex/Gender

More males (1,409,288 or 60.30%) than females (895,404 or 38.31%) were enrolled in aggregate Domestic Intramural Research Protocols.
 More minority males (286,978 or 62.47%) than females (172,273 or 37.50%) were enrolled in aggregate Domestic Intramural Research Protocols.

Race

Approximately 19.66% (459,360) of participants in aggregate Domestic Intramural Research (2,337,022 total) were classified as U.S. minorities.
 Largest identified racial group was White at 60.73% following the 1977 OMB standards and 73.64% 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 Black or African American at 11.12% following the 1997 OMB standards.
 According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.21%.
 According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.15%.

Ethnicity

3.64% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.
 For participants reporting ethnicity as Hispanic/Latino:
 Largest identified racial group was White at 73.95% (2nd largest category was Unknown/Other at 21.44%).
 Smallest identified racial group was Asian at 0.06%.
 Of the 77,927 participants, 45.86% were women and 54.11% were men.
 4.02% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 10A. DOMESTIC Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	345,372	67,801		19.63%
%	59.04%	57.52%		
Males	223,021	49,563		22.22%
%	38.12%	42.05%		
Unknown	16,630	505		3.04%
%	2.84%	0.43%		
TOTAL	585,023	117,869	20.15%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 552

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 401			
	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	1388	2963	15147	334	149433	6534	11012	186,811	155829	22175	8807	186,811
	0.39%	0.83%	4.22%	0.09%	41.64%	1.82%	3.07%	52.05%	43.42%	6.18%	2.45%	52.05%
	0.74%	1.59%	8.11%	0.18%	79.99%	3.50%	5.89%	100.00%	83.42%	11.87%	4.71%	100.00%
Male	56.68%	47.85%	60.97%	52.52%	54.33%	55.22%	29.08%	52.05%	54.27%	52.91%	29.54%	52.05%
	1043	3182	9628	298	124381	5174	11759	155,465	130073	19409	5983	155,465
	0.29%	0.89%	2.68%	0.08%	34.66%	1.44%	3.28%	43.32%	36.24%	5.41%	1.67%	43.32%
Unknown	0.67%	2.05%	6.19%	0.19%	80.01%	3.33%	7.56%	100.00%	83.67%	12.48%	3.85%	100.00%
	42.59%	51.39%	38.76%	46.86%	45.22%	43.73%	31.06%	43.32%	45.30%	46.31%	20.07%	43.32%
	18	47	68	4	1257	124	15092	16,610	1254	330	15026	16,610
Total	0.01%	0.01%	0.02%	0.00%	0.35%	0.03%	4.21%	4.63%	0.35%	0.09%	4.19%	4.63%
	0.11%	0.28%	0.41%	0.02%	7.57%	0.75%	90.86%	100.00%	7.55%	1.99%	90.46%	100.00%
	0.73%	0.76%	0.27%	0.63%	0.46%	1.05%	39.86%	4.63%	0.44%	0.79%	50.40%	4.63%
Total	2,449	6,192	24,843	636	275,071	11,832	37,863	358,886	287,156	41,914	29,816	358,886
	0.68%	1.73%	6.92%	0.18%	76.65%	3.30%	10.55%	100.00%	80.01%	11.68%	8.31%	100.00%
	0.68%	1.73%	6.92%	0.18%	76.65%	3.30%	10.55%	100.00%	80.01%	11.68%	8.31%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	298	95	336	65	12571	3170	5640	22,175	44,577
	0.71%	0.23%	0.80%	0.16%	29.99%	7.56%	13.46%	52.91%	12.42%
	1.34%	0.43%	1.52%	0.29%	56.68%	14.30%	25.43%	100.00%	23.86%
Male	57.64%	41.67%	47.06%	53.28%	56.52%	59.05%	44.33%	52.91%	55.09%
	212	126	370	54	9559	2136	6952	19,409	35,836
	0.51%	0.30%	0.88%	0.13%	22.81%	5.10%	16.59%	46.31%	9.99%
Unknown	1.09%	0.65%	1.91%	0.28%	49.25%	11.01%	36.82%	100.00%	23.05%
	41.01%	55.26%	51.82%	44.26%	42.98%	39.79%	54.64%	46.31%	44.29%
	7	7	8	3	111	62	132	330	504
TOTAL	0.02%	0.02%	0.02%	0.01%	0.26%	0.15%	0.31%	0.79%	0.14%
	2.12%	2.12%	2.42%	0.91%	33.64%	18.79%	40.00%	100.00%	3.03%
	1.35%	3.07%	1.12%	2.46%	0.50%	1.15%	1.04%	0.79%	0.62%
TOTAL	517	228	714	122	22,241	5,368	12,724	41,914	80,917
	1.23%	0.54%	1.70%	0.29%	53.06%	12.81%	30.36%	100.00%	22.55%
	1.23%	0.54%	1.70%	0.29%	53.06%	12.81%	30.36%	100.00%	22.55%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 10A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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	637	3,413	13,503	5,671	132,780	2,557	158,561	23,224
	0.28%	1.51%	5.97%	2.51%	58.72%	1.13%	70.12%	10.27%
	<i>0.40%</i>	<i>2.15%</i>	<i>8.52%</i>	<i>3.58%</i>	<i>83.74%</i>	<i>1.61%</i>	<i>100.00%</i>	<i>14.65%</i>
	72.39%	76.83%	61.19%	59.31%	71.76%	61.57%	70.12%	62.85%
Male	243	1,029	8,565	3,890	52,244	1,585	67,556	13,727
	0.11%	0.46%	3.79%	1.72%	23.10%	0.70%	29.87%	6.07%
	<i>0.36%</i>	<i>1.52%</i>	<i>12.68%</i>	<i>5.76%</i>	<i>77.33%</i>	<i>2.35%</i>	<i>100.00%</i>	<i>20.32%</i>
	27.61%	23.17%	38.81%	40.69%	28.24%	38.17%	29.87%	37.15%
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%
	<i>0.00%</i>	<i>0.00%</i>	<i>5.00%</i>	<i>0.00%</i>	<i>40.00%</i>	<i>55.00%</i>	<i>100.00%</i>	<i>5.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.26%	0.01%	0.00%
Total	880	4,442	22,069	9,561	185,032	4,153	226,137	36,952
	0.39%	1.96%	9.76%	4.23%	81.82%	1.84%	100.00%	16.34%
	<i>0.39%</i>	<i>1.96%</i>	<i>9.76%</i>	<i>4.23%</i>	<i>81.82%</i>	<i>1.84%</i>	<i>100.00%</i>	<i>16.34%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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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 (345,372 or 59.04%) than males (223,021 or 38.12%) were enrolled in aggregate Domestic Extramural Phase III Research Protocols. More minority females (67,801 or 57.52%) than males (49,563 or 42.05%) are enrolled in aggregate Domestic Extramural Phase III Research Protocols.

Race

Approximately 20.15% (117,869) of participants in aggregate Domestic Extramural Phase III Research (585,023 total) were classified as U.S. minorities. Largest identified racial group was White at 81.82% following the 1977 OMB standards and 76.65% following the 1997 OMB standards. Largest identified racial minority group was Black or African American at 9.76% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 6.92% following the 1997 OMB standards. According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.18%. According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.39%.

Ethnicity

11.68% 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 53.06% (2nd largest category was Unknown/Other at 30.36%). Smallest identified racial group was Hawaiian/Pacific Islander at 0.29%. Of the 41,914 participants, 52.91% were women and 46.31% were men. 4.23% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 11A. DOMESTIC Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	2,610	871		33.37%
%	42.91%	50.85%		
Males	3,245	829		25.55%
%	53.35%	48.39%		
Unknown	227	13		0.00%
%	3.73%	0.76%		
TOTAL	6,082	1,713	28.17%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	33
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II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 22			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	6	36	537	77	695	2	102	1,455	1,269	42	144	1,455
	0.21%	1.25%	18.70%	2.68%	24.21%	0.07%	3.55%	50.68%	44.20%	1.46%	5.02%	50.68%
	0.41%	2.47%	36.91%	5.29%	47.77%	0.14%	7.01%	100.00%	87.22%	2.89%	9.90%	100.00%
	85.71%	29.51%	59.01%	100.00%	52.06%	50.00%	24.52%	50.68%	53.57%	47.19%	34.87%	50.68%
Male	1	86	360	0	640	2	100	1,189	1,087	47	55	1,189
	0.03%	3.00%	12.54%	0.00%	22.29%	0.07%	3.48%	41.41%	37.86%	1.64%	1.92%	41.41%
	0.08%	7.23%	30.28%	0.00%	53.83%	0.17%	8.41%	100.00%	91.42%	3.95%	4.63%	100.00%
	14.29%	70.49%	39.56%	0.00%	47.94%	50.00%	24.04%	41.41%	45.88%	52.81%	13.32%	41.41%
Unknown	0	0	13	0	0	0	214	227	13	0	214	227
	0.00%	0.00%	0.45%	0.00%	0.00%	0.00%	7.45%	7.91%	0.45%	0.00%	7.45%	7.91%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	1.43%	0.00%	0.00%	0.00%	51.44%	7.91%	0.55%	0.00%	51.82%	7.91%
Total	7	122	910	77	1,335	4	416	2,871	2,369	89	413	2,871
	0.24%	4.25%	31.70%	2.68%	46.50%	0.14%	14.49%	100.00%	82.51%	3.10%	14.39%	100.00%
	0.24%	4.25%	31.70%	2.68%	46.50%	0.14%	14.49%	100.00%	82.51%	3.10%	14.39%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	1	0	0	0	2	1	38	42	698
	1.12%	0.00%	0.00%	0.00%	2.25%	1.12%	42.70%	47.19%	24.31%
	2.38%	0.00%	0.00%	0.00%	4.76%	2.38%	90.48%	100.00%	47.97%
	100.00%	0.00%	0.00%	0.00%	66.67%	100.00%	45.24%	47.19%	57.83%
Male	0	0	0	0	1	0	46	47	496
	0.00%	0.00%	0.00%	0.00%	1.12%	0.00%	51.69%	52.81%	17.28%
	0.00%	0.00%	0.00%	0.00%	2.13%	0.00%	97.87%	100.00%	41.72%
	0.00%	0.00%	0.00%	0.00%	33.33%	0.00%	54.76%	52.81%	41.09%
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%	0.45%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	1.08%
TOTAL	1	0	0	0	3	1	84	89	1,207
	1.12%	0.00%	0.00%	0.00%	3.37%	1.12%	94.38%	100.00%	42.04%
	1.12%	0.00%	0.00%	0.00%	3.37%	1.12%	94.38%	100.00%	42.04%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 11A

Number of Protocols with Enrollment Data:

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III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Subtotal Using US Minority Categories (shaded): OLD FORM
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	
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%
	<i>0.17%</i>	<i>1.99%</i>	<i>10.48%</i>	<i>2.34%</i>	<i>84.59%</i>	<i>0.43%</i>	<i>100.00%</i>	<i>14.98%</i>
	40.00%	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%
	<i>0.15%</i>	<i>1.99%</i>	<i>11.72%</i>	<i>2.33%</i>	<i>83.17%</i>	<i>0.63%</i>	<i>100.00%</i>	<i>16.20%</i>
	60.00%	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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>
	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%
	<i>0.16%</i>	<i>1.99%</i>	<i>11.27%</i>	<i>2.34%</i>	<i>83.68%</i>	<i>0.56%</i>	<i>100.00%</i>	<i>15.76%</i>
	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 (3,245 or 53.35%) than females (2,610 or 42.91%) were enrolled in aggregate Domestic Intramural Phase III Research Protocols. More minority females (871 or 50.85%) than males (829 or 48.39%) were enrolled in aggregate Domestic Intramural Phase III Research Protocols.

Race

Approximately 28.17% (1,713) of participants in aggregate Domestic Intramural Phase III Research (6,082 total) were classified as U.S. minorities. Largest identified racial group was White at 83.68% following the 1977 OMB standards and 46.50% 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 31.70% following the 1997 OMB standards. According to the 1997 OMB standards, the smallest identified racial minority was More Than One Race at 0.14%. According to the 1977 OMB standards, the smallest identified racial minority was American Indian/Alaska Native at 0.16%.

Ethnicity

3.10% 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 94.38% (2nd largest category was White at 3.37%). Asian, Black or African American and Hawaiian/Pacific Islander were the smallest identified racial groups with 0.0%. Of the 89 participants, 47.19% were women and 52.81% were men. 2.34% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 12A. FOREIGN Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	729,198	493,689		67.70%
%	57.07%	57.08%		
Males	540,115	367,262		68.00%
%	42.27%	42.46%		
Unknown	8,415	3,994		47.46%
%	0.66%	0.46%		
TOTAL	1,277,728	864,945	67.69%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 497

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 491			
	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	10,807	269,230	133,774	3,431	233,242	6,913	69,163	726,560	589,414	97,660	39,486	726,560
	0.85%	21.14%	10.50%	0.27%	18.31%	0.54%	5.43%	57.04%	46.28%	7.67%	3.10%	57.04%
	1.49%	37.06%	18.41%	0.47%	32.10%	0.95%	9.52%	100.00%	81.12%	13.44%	5.43%	100.00%
	50.93%	59.96%	51.77%	50.49%	57.77%	51.57%	57.15%	57.04%	57.68%	56.87%	49.34%	57.04%
Male	10,276	179,016	123,068	3,364	167,854	6,461	48,649	538,688	428,912	72,483	37,293	538,688
	0.81%	14.06%	9.66%	0.26%	13.18%	0.51%	3.82%	42.29%	33.68%	5.69%	2.93%	42.29%
	1.91%	33.23%	22.85%	0.62%	31.16%	1.20%	9.03%	100.00%	79.62%	13.46%	6.92%	100.00%
	48.43%	39.87%	47.62%	49.51%	41.57%	48.20%	40.20%	42.29%	41.97%	42.21%	46.60%	42.29%
Unknown	135	788	1,583	0	2670	31	3,208	8,415	3,586	1,585	3,244	8,415
	0.01%	0.06%	0.12%	0.00%	0.21%	0.00%	0.25%	0.66%	0.28%	0.12%	0.25%	0.66%
	1.60%	9.36%	18.81%	0.00%	31.73%	0.37%	38.12%	100.00%	42.61%	18.84%	38.55%	100.00%
	0.64%	0.18%	0.61%	0.00%	0.66%	0.23%	2.65%	0.66%	0.35%	0.92%	4.05%	0.66%
Total	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
	1.67%	35.26%	20.29%	0.53%	31.70%	1.05%	9.50%	100.00%	80.23%	13.48%	6.28%	100.00%
	1.67%	35.26%	20.29%	0.53%	31.70%	1.05%	9.50%	100.00%	80.23%	13.48%	6.28%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	9,990	12260	552	1	27,021	5,775	42,061	97,660	493,237
	5.82%	7.14%	0.32%	0.00%	15.73%	3.36%	24.49%	56.87%	38.73%
	10.23%	12.55%	0.57%	0.00%	27.67%	5.91%	43.07%	100.00%	67.89%
	50.54%	50.01%	52.98%	100.00%	54.05%	51.32%	64.55%	56.87%	57.09%
Male	9,656	12255	490	0	22,967	5,470	21,645	72,483	366,797
	5.62%	7.14%	0.29%	0.00%	13.37%	3.19%	12.60%	42.21%	28.80%
	13.32%	16.91%	0.68%	0.00%	31.69%	7.55%	29.86%	100.00%	68.09%
	48.85%	49.99%	47.02%	0.00%	45.94%	48.61%	33.22%	42.21%	42.45%
Unknown	120	0	0	0	7	8	1,450	1,585	3,994
	0.07%	0.00%	0.00%	0.00%	0.00%	0.00%	0.84%	0.92%	0.31%
	7.57%	0.00%	0.00%	0.00%	0.44%	0.50%	91.48%	100.00%	47.46%
	0.61%	0.00%	0.00%	0.00%	0.01%	0.07%	2.23%	0.92%	0.46%
TOTAL	19,766	24,515	1,042	1	49,995	11,253	65,156	171,728	864,028
	11.51%	14.28%	0.61%	0.00%	29.11%	6.55%	37.94%	100.00%	67.84%
	11.51%	14.28%	0.61%	0.00%	29.11%	6.55%	37.94%	100.00%	67.84%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 12A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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	15	36	13	388	2,097	89	2,638	452
	0.37%	0.89%	0.32%	9.54%	51.59%	2.19%	64.90%	11.12%
	<i>0.57%</i>	<i>1.36%</i>	<i>0.49%</i>	<i>14.71%</i>	<i>79.49%</i>	<i>3.37%</i>	<i>100.00%</i>	<i>17.13%</i>
	0.00%	100.00%	92.86%	45.54%	68.60%	97.80%	64.90%	49.29%
Male	0	0	1	464	960	2	1,427	465
	0.00%	0.00%	0.02%	11.41%	23.62%	0.05%	35.10%	11.44%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.07%</i>	<i>32.52%</i>	<i>67.27%</i>	<i>0.14%</i>	<i>100.00%</i>	<i>32.59%</i>
	0.00%	0.00%	7.14%	54.46%	31.40%	2.20%	35.10%	50.71%
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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	15	36	14	852	3,057	91	4,065	917
	0.37%	0.89%	0.34%	20.96%	75.20%	2.24%	100.00%	22.56%
	<i>0.37%</i>	<i>0.89%</i>	<i>0.34%</i>	<i>20.96%</i>	<i>75.20%</i>	<i>2.24%</i>	<i>100.00%</i>	<i>22.56%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

6

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 (729,198 or 57.07%) than males (540,115 or 42.27%) were enrolled in aggregate Foreign Intramural and Extramural Research Protocols. More minority females (493,689 or 57.08%) than males (367,262 or 42.46%) were enrolled in aggregate Foreign Intramural and Extramural Research Protocols.

Race

Approximately 67.69% (864,945) of participants in aggregate Foreign Intramural and Extramural Research (1,277,728 total) were classified as minorities. Largest identified racial group was White at 75.20% and Hispanic at 20.96% following the 1977 OMB standards. Largest identified racial group was Asian at 35.26% following the 1997 OMB standards (with 31.70%, White was not the largest identified racial group). According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.53%. According to the 1977 OMB standards, the smallest identified racial minority was Black or African American at 0.34%.

Ethnicity

13.48% 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 37.94% (2nd largest category was White at 29.11%). Smallest identified racial group was Hawaiian/Pacific Islander at 0.00%. Of the 171,728 participants, 56.87% were women and 42.21% were men. 20.96% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

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

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	410,523	316,669		77.14%
%	52.68%	52.50%		
Males	363,542	282,867		77.81%
%	46.65%	46.90%		
Unknown	5,199	3,588		69.01%
%	0.67%	0.59%		
TOTAL	779,264	603,124	77.40%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 410

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 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	10,803	121,385	129,224	3,429	100,256	3,860	38,928	407,885	313,672	73,056	21,157	407,885
	1.39%	15.66%	16.67%	0.44%	12.93%	0.50%	5.02%	52.62%	40.46%	9.42%	2.73%	52.62%
	2.65%	29.76%	31.68%	0.84%	24.58%	0.95%	9.54%	100.00%	76.90%	17.91%	5.19%	100.00%
	50.92%	53.52%	52.03%	50.48%	53.46%	52.26%	50.49%	52.62%	53.19%	51.35%	49.03%	52.62%
Male	10,276	105,024	117,553	3,364	87,004	3,495	35,399	362,115	275,289	67,643	19,183	362,115
	1.33%	13.55%	15.16%	0.43%	11.22%	0.45%	4.57%	46.71%	35.51%	8.73%	2.47%	46.71%
	2.84%	29.00%	32.46%	0.93%	24.03%	0.97%	9.78%	100.00%	76.02%	18.68%	5.30%	100.00%
	48.44%	46.31%	47.33%	49.52%	46.39%	47.32%	45.91%	46.71%	46.68%	47.54%	44.45%	46.71%
Unknown	135	395	1,570	0	292	31	2,776	5,199	802	1,585	2,812	5,199
	0.02%	0.05%	0.20%	0.00%	0.04%	0.00%	0.36%	0.67%	0.10%	0.20%	0.36%	0.67%
	2.60%	7.60%	30.20%	0.00%	5.62%	0.60%	53.39%	100.00%	15.43%	30.49%	54.09%	100.00%
	0.64%	0.17%	0.63%	0.00%	0.16%	0.42%	3.60%	0.67%	0.14%	1.11%	6.52%	0.67%
Total	21,214	226,804	248,347	6,793	187,552	7,386	77,103	775,199	589,763	142,284	43,152	775,199
	2.74%	29.26%	32.04%	0.88%	24.19%	0.95%	9.95%	100.00%	76.08%	18.35%	5.57%	100.00%
	2.74%	29.26%	32.04%	0.88%	24.19%	0.95%	9.95%	100.00%	76.08%	18.35%	5.57%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	9,986	12,260	439	0	26,288	2,855	21,228	73,056	316,217
	7.02%	8.62%	0.31%	0.00%	18.48%	2.01%	14.92%	51.35%	40.79%
	13.67%	16.78%	0.60%	0.00%	35.98%	3.91%	29.06%	100.00%	77.53%
	50.53%	50.01%	50.23%	0.00%	53.83%	52.19%	49.56%	51.35%	52.51%
Male	9,656	12,255	435	0	22,538	2,607	20,152	67,643	282,402
	6.79%	8.61%	0.31%	0.00%	15.84%	1.83%	14.16%	47.54%	36.43%
	14.27%	18.12%	0.64%	0.00%	33.32%	3.85%	29.79%	100.00%	77.99%
	48.86%	49.99%	49.77%	0.00%	46.15%	47.66%	47.05%	47.54%	46.89%
Unknown	120	0	0	0	7	8	1,450	1,585	3,588
	0.08%	0.00%	0.00%	0.00%	0.00%	0.01%	1.02%	1.11%	0.46%
	7.57%	0.00%	0.00%	0.00%	0.44%	0.50%	91.48%	100.00%	69.01%
	0.61%	0.00%	0.00%	0.00%	0.01%	0.15%	3.39%	1.11%	0.60%
TOTAL	19,762	24,515	874	0	48,833	5,470	42,830	142,284	602,207
	13.89%	17.23%	0.61%	0.00%	34.32%	3.84%	30.10%	100.00%	77.68%
	13.89%	17.23%	0.61%	0.00%	34.32%	3.84%	30.10%	100.00%	77.68%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 13A

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

Number of Protocols with Enrollment Data:

	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	15	36	13	388	2,097	89	2,638	452
	0.37%	0.89%	0.32%	9.54%	51.59%	2.19%	64.90%	11.12%
	<i>0.57%</i>	<i>1.36%</i>	<i>0.49%</i>	<i>14.71%</i>	<i>79.49%</i>	<i>3.37%</i>	<i>100.00%</i>	<i>17.13%</i>
	0.00%	100.00%	92.86%	45.54%	68.60%	97.80%	64.90%	49.29%
Male	0	0	1	464	960	2	1,427	465
	0.00%	0.00%	0.02%	11.41%	23.62%	0.05%	35.10%	11.44%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.07%</i>	<i>32.52%</i>	<i>67.27%</i>	<i>0.14%</i>	<i>100.00%</i>	<i>32.59%</i>
	0.00%	0.00%	7.14%	54.46%	31.40%	2.20%	35.10%	50.71%
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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	15	36	14	852	3,057	91	4,065	917
	0.37%	0.89%	0.34%	20.96%	75.20%	2.24%	100.00%	22.56%
	<i>0.37%</i>	<i>0.89%</i>	<i>0.34%</i>	<i>20.96%</i>	<i>75.20%</i>	<i>2.24%</i>	<i>100.00%</i>	<i>22.56%</i>
	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 (410,523 or 52.68%) than males (363,542 or 46.65%) were enrolled in aggregate Foreign Extramural Research Protocols. More minority females (316,669 or 52.50%) than males (282,867 or 46.90%) were enrolled in aggregate Foreign Extramural Research Protocols.

Race

Approximately 77.40% (603,124) of participants in aggregate Foreign Extramural Research (779,264 total) were classified as minorities. Largest identified racial group was White at 75.20% following the 1977 OMB standards. Largest identified racial group was Black or African American at 32.04% following the 1997 OMB standards. Largest identified racial minority group was Hispanic at 20.96% following the 1977 OMB standards. Largest identified racial minority group was Black or African American at 32.04% following the 1997 OMB standards. According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.88%. According to the 1977 OMB standards, the smallest identified racial minority was Black or African American at 0.34%.

Ethnicity

18.35% 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 34.32% (2nd largest category was Unknown/Other at 30.10%). Smallest identified racial group was Hawaiian/Pacific Islander at 0.00%. Of the 142,284 participants, 51.35% were women and 47.54% were men. 20.96% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

Table 14A. FOREIGN Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	318,675	177,020		55.55%
%	63.93%	67.61%		
Males	176,573	84,395		47.80%
%	35.42%	32.23%		
Unknown	3,216	406		12.62%
%	0.65%	0.16%		
TOTAL	498,464	261,821	52.53%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 87

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 87			
	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	147,845	4,550	2	132,986	3,053	30,235	318,675	275,742	24,604	18,329	318,675
	0.00%	29.66%	0.91%	0.00%	26.68%	0.61%	6.07%	63.93%	55.32%	4.94%	3.68%	63.93%
	0.00%	46.39%	1.43%	0.00%	41.73%	0.96%	9.49%	100.00%	86.53%	7.72%	5.75%	100.00%
	100.00%	66.53%	45.15%	100.00%	61.51%	50.72%	68.85%	63.93%	63.81%	83.56%	49.71%	63.93%
Male	0	73,992	5,515	0	80,850	2,966	13,250	176,573	153,623	4,840	18,110	176,573
	0.00%	14.84%	1.11%	0.00%	16.22%	0.60%	2.66%	35.42%	30.82%	0.97%	3.63%	35.42%
	0.00%	41.90%	3.12%	0.00%	45.79%	1.68%	7.50%	100.00%	87.00%	2.74%	10.28%	100.00%
	0.00%	33.30%	54.72%	0.00%	37.39%	49.28%	30.17%	35.42%	35.55%	16.44%	49.12%	35.42%
Unknown	0	393	13	0	2,378	0	432	3,216	2,784	0	432	3,216
	0.00%	0.08%	0.00%	0.00%	0.48%	0.00%	0.00%	0.65%	0.56%	0.00%	0.09%	0.65%
	0.00%	12.22%	0.40%	0.00%	73.94%	0.00%	13.43%	100.00%	86.57%	0.00%	13.43%	100.00%
	0.00%	0.18%	0.13%	0.00%	1.10%	0.00%	0.98%	0.65%	0.64%	0.00%	1.17%	0.65%
Total	4	222,230	10,078	2	216,214	6,019	43,917	498,464	432,149	29,444	36,871	498,464
	0.00%	44.58%	2.02%	0.00%	43.38%	1.21%	8.81%	100.00%	86.70%	5.91%	7.40%	100.00%
	0.00%	44.58%	2.02%	0.00%	43.38%	1.21%	8.81%	100.00%	86.70%	5.91%	7.40%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	4	0	113	1	733	2,920	20,833	24,604	177,020
	0.01%	0.00%	0.38%	0.00%	2.49%	9.92%	70.75%	83.56%	35.51%
	0.02%	0.00%	0.46%	0.00%	2.98%	11.87%	84.67%	100.00%	55.55%
	100.00%	0.00%	67.26%	100.00%	63.08%	50.49%	93.31%	83.56%	67.61%
Male	0	0	55	0	429	2,863	1,493	4,840	84,395
	0.00%	0.00%	0.19%	0.00%	1.46%	9.72%	5.07%	16.44%	16.93%
	0.00%	0.00%	1.14%	0.00%	8.86%	59.15%	30.85%	100.00%	47.80%
	0.00%	0.00%	32.74%	0.00%	36.92%	49.51%	6.69%	16.44%	32.23%
Unknown	0	0	0	0	0	0	0	0	406
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.08%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	12.62%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.16%
TOTAL	4	0	168	1	1,162	5,783	22,326	29,444	261,821
	0.01%	0.00%	0.57%	0.00%	3.95%	19.64%	75.83%	100.00%	52.53%
	0.01%	0.00%	0.57%	0.00%	3.95%	19.64%	75.83%	100.00%	52.53%
	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 14A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
Total	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>

0

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 (318,675 or 63.93%) than males (176,573 or 35.42%) were enrolled in aggregate Foreign intramural research protocols. More minority females (177,020 or 67.61%) than males (84,395 or 32.23%) were enrolled in aggregate Foreign intramural research protocols.

Race

Approximately 52.53% (261,821) of participants in aggregate Foreign intramural research (498,464 total) were classified as minorities. Largest identified racial group was Asian at 44.58% following the 1997 OMB standards. According to the 1997 OMB standards, the smallest identified racial minorities were Hawaiian/Pacific Islander and American Indian/Alaska Native both at 0.0%. Data represented in Table 18A required no foreign reporting using the 1977 OMB Standards.

Ethnicity

5.91% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. For participants reporting ethnicity as Hispanic/Latino: Largest identified racial group was Unknown/Other at 75.83%. Smallest identified racial groups were Asian and Hawaiian/Pacific Islander and Hawaiian/Pacific Islander at 0.0%. Of the 29,444 participants, 83.56% were women and 16.44% were men.

Table 15A. FOREIGN Aggregate Enrollment Data for Phase III Extramural Research Protocols Funded in FY2007 and Reported in FY2008: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	98,685	93,291		94.53%
%	51.66%	51.49%		
Males	91,949	87,520		95.18%
%	48.14%	48.30%		
Unknown	377	377		100.00%
%	0.20%	0.21%		
TOTAL	191,011	181,188	94.86%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 50

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 48			
	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	6,230	46,145	39,592	2	2,379	2	2,091	96,441	88,097	7,478	866	96,441
	3.32%	24.57%	21.08%	0.00%	1.27%	0.00%	1.11%	51.35%	46.91%	3.98%	0.46%	51.35%
	6.46%	47.85%	41.05%	0.00%	2.47%	0.00%	2.17%	100.00%	91.35%	7.75%	0.90%	100.00%
	49.64%	51.86%	51.24%	66.67%	48.07%	0.66%	55.55%	51.35%	51.46%	50.37%	49.01%	51.35%
Male	6,285	42,781	37,448	1	2,570	299	1,613	90,997	82,823	7,273	901	90,997
	3.35%	22.78%	19.94%	0.00%	1.37%	0.16%	0.86%	48.45%	44.10%	3.87%	0.48%	48.45%
	6.91%	47.01%	41.15%	0.00%	2.82%	0.33%	1.77%	100.00%	91.02%	7.99%	0.99%	100.00%
	50.08%	48.08%	48.47%	33.33%	51.93%	99.34%	42.85%	48.45%	48.38%	48.99%	50.99%	48.45%
Unknown	35	56	226	0	0	0	60	377	282	95	0	377
	0.02%	0.03%	0.12%	0.00%	0.00%	0.00%	0.03%	0.20%	0.15%	0.05%	0.00%	0.20%
	9.28%	14.85%	59.95%	0.00%	0.00%	0.00%	15.92%	100.00%	74.80%	25.20%	0.00%	100.00%
	0.28%	0.06%	0.29%	0.00%	0.00%	0.00%	1.59%	0.20%	0.16%	0.64%	0.00%	0.20%
Total	12,550	88,982	77,266	3	4,949	301	3,764	187,815	171,202	14,846	1,767	187,815
	6.68%	47.38%	41.14%	0.00%	2.64%	0.16%	2.00%	100.00%	91.15%	7.90%	0.94%	100.00%
	6.68%	47.38%	41.14%	0.00%	2.64%	0.16%	2.00%	100.00%	91.15%	7.90%	0.94%	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								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	6,226	0	1	0	34	0	1,217	7,478	93,222
	41.94%	0.00%	0.01%	0.00%	0.23%	0.00%	8.20%	50.37%	49.64%
	83.26%	0.00%	0.01%	0.00%	0.45%	0.00%	16.27%	100.00%	96.66%
	49.66%	#DIV/0!	100.00%	0.00%	26.15%	0.00%	64.56%	50.37%	51.47%
Male	6,277	0	0	0	96	292	608	7,273	87,518
	42.28%	0.00%	0.00%	0.00%	0.65%	1.97%	4.10%	48.99%	46.60%
	86.31%	0.00%	0.00%	0.00%	1.32%	4.01%	8.36%	100.00%	96.18%
	50.06%	#DIV/0!	0.00%	0.00%	73.85%	100.00%	32.25%	48.99%	48.32%
Unknown	35	0	0	0	0	0	60	95	377
	0.24%	0.00%	0.00%	0.00%	0.00%	0.00%	0.40%	0.64%	0.20%
	36.84%	0.00%	0.00%	0.00%	0.00%	0.00%	63.16%	100.00%	100.00%
	0.28%	#DIV/0!	0.00%	0.00%	0.00%	0.00%	3.18%	0.64%	0.21%
TOTAL	12,538	0	1	0	130	292	1,885	14,846	181,117
	84.45%	0.00%	0.01%	0.00%	0.88%	1.97%	12.70%	100.00%	96.43%
	84.45%	0.00%	0.01%	0.00%	0.88%	1.97%	12.70%	100.00%	96.43%
	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Table 15A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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	15	36	13	5	2,086	89	2,244	69
	0.47%	1.13%	0.41%	0.16%	65.27%	2.78%	70.21%	2.16%
	<i>0.67%</i>	<i>1.60%</i>	<i>0.58%</i>	<i>0.22%</i>	<i>92.96%</i>	<i>3.97%</i>	<i>100.00%</i>	<i>3.07%</i>
	0.00%	100.00%	92.86%	83.33%	68.75%	97.80%	70.21%	97.18%
Male	0	0	1	1	948	2	952	2
	0.00%	0.00%	0.03%	0.03%	29.66%	0.06%	29.79%	0.06%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.11%</i>	<i>0.11%</i>	<i>99.58%</i>	<i>0.21%</i>	<i>100.00%</i>	<i>0.21%</i>
	0.00%	0.00%	7.14%	16.67%	31.25%	2.20%	29.79%	2.82%
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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	15	36	14	6	3,034	91	3,196	71
	0.47%	1.13%	0.44%	0.19%	94.93%	2.85%	100.00%	2.22%
	<i>0.47%</i>	<i>1.13%</i>	<i>0.44%</i>	<i>0.19%</i>	<i>94.93%</i>	<i>2.85%</i>	<i>100.00%</i>	<i>2.22%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

2

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 (98,685; 51.66%) than males (91,949; 48.14%) were enrolled in Aggregate Foreign Phase III Extramural Research Protocols.
 More minority females (93,291; 51.49%) than males (87,520; 48.30%) were enrolled in Aggregate Foreign Phase III Extramural Research Protocols.

Race

Approximately 94.86% (181,188) of participants in aggregate Foreign Phase III Extramural Research (191,011 total) were classified as minorities.
 Largest identified racial group was White at 94.93% following the 1977 OMB standards.
 Largest identified racial group was Asian at 47.38% following the 1997 OMB standards.
 Largest identified racial minority groups was Asian/Pacific Islander at 1.13% following the 1977 OMB standards.
 Largest identified racial minority group was Asian at 47.38% following the 1997 OMB standards.
 According to the 1997 OMB standards, the smallest identified racial minority was Hawaiian/Pacific Islander at 0.0%.
 According to the 1977 OMB standards, the smallest identified racial minority was Hispanic at 0.19%.

Ethnicity

7.90% 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 American Indian/Alaska Native at 84.45% (2nd largest category was Unknown/Other at 12.70%).
 Smallest identified racial groups were Asian and Hawaiian/Pacific Islander at 0.00%.
 Of the 14,846 participants, 50.37% were women and 48.99% were men.
 0.19% of participants identified their ethnicity as Hispanic according to the 1977 OMB standards.

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

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	8,923	7,577		84.92%
	85.29%	98.88%		
Males	1,539	86		5.59%
	14.71%	1.12%		
Unknown	0	0		0.00%
	0.00%	0.00%		
TOTAL	10,462	7,663	73.25%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:	4
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II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data:			
	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	8,831	8,923	92	7,485	1,346	8,923
	0.00%	0.00%	0.88%	0.00%	0.00%	0.00%	84.41%	85.29%	0.88%	71.54%	12.87%	85.29%
	0.00%	0.00%	1.03%	0.00%	0.00%	0.00%	98.97%	100.00%	1.03%	83.88%	15.08%	100.00%
	0.00%	0.00%	59.35%	0.00%	0.00%	0.00%	85.68%	85.29%	59.35%	99.69%	48.09%	85.29%
Male	0	0	63	0	0	0	1,476	1,539	63	23	1,453	1,539
	0.00%	0.00%	0.60%	0.00%	0.00%	0.00%	14.11%	14.71%	0.60%	0.22%	13.89%	14.71%
	0.00%	0.00%	4.09%	0.00%	0.00%	0.00%	95.91%	100.00%	4.09%	1.49%	94.41%	100.00%
	0.00%	0.00%	40.65%	0.00%	0.00%	0.00%	14.32%	14.71%	40.65%	0.31%	51.91%	14.71%
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	10,307	10,462	155	7,508	2,799	10,462
	0.00%	0.00%	1.48%	0.00%	0.00%	0.00%	98.52%	100.00%	1.48%	71.76%	26.75%	100.00%
	0.00%	0.00%	1.48%	0.00%	0.00%	0.00%	98.52%	100.00%	1.48%	71.76%	26.75%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	
Female	0	0	0	0	0	0	7,485	7,485	7,577
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	99.69%	99.69%	72.42%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	84.92%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	99.69%	99.69%	98.88%
Male	0	0	0	0	0	0	23	23	86
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.31%	0.31%	0.82%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	5.59%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.31%	0.31%	1.12%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	#DIV/0!	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	0	7,508	7,508	7,663
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	73.25%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	73.25%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%

Table 16A

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								Number of Protocols with Enrollment Data:
	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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
	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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
	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%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

0

Legend

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

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

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

Data Table Comments:

Sex/Gender:

More females (8,923; 85.29%) than males (1,539; 14.71%) were enrolled in aggregate Foreign Phase III Intramural Research Protocols. More minority females (7,577; 98.88%) than males (86; 1.12%) were enrolled in aggregate Foreign Phase III Intramural Research Protocols.

Race

Approximately 73.25% (7,663) of participants in aggregate Foreign Phase III Intramural Research (10,462 total) were classified as minorities. Largest identified racial group was Unknown/Other at 98.52% following the 1997 OMB standards. Largest identified racial minority group was Black/African American at 1.48% following the 1997 OMB standards. According to the 1997 OMB standards the smallest identified racial minorities were, American Indian/Alaska Native, Asian, and Hawaiian/Pacific Islander at 0.0%. The data represented in Table 20A required no foreign reporting using the 1977 OMB Standards.

Ethnicity

71.76% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. For participants reporting ethnicity as Hispanic/Latino: Largest identified racial group was Unknown/Other at 100%. Of the 7,508 participants, 99.69% were women and 0.31% were men.