

Department of Health and Human Services
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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 2004 and Fiscal Year 2005

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

Historical Perspectives

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

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

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

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

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

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

of outreach activities were initiated to explain the revised policy to the scientific research community and to clear up common misunderstandings about the new requirements.

Continuing Implementation and Monitoring Activities

Following a Congressional request for an assessment of NIH's progress in implementing 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.

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

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

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

- ▶ **Updating the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research** and posting it on the ORWH home page <http://orwh.od.nih.gov/inclusion.html> and NIH web page, *Inclusion of Women and Minorities Policy Implementation* at: http://grants.nih.gov/grants/funding/women_min/women_min.htm.
- ▶ **Developing a new term and condition of award** statement for awards made after October 1, 2000 that have NIH-defined Phase III clinical trials.
- ▶ **Incorporating language in the NIH solicitations for grant applications and contract proposals to clarify the submission requirement for NIH-defined Phase III clinical trials**, a description of plans for sex/gender and/or race/ethnicity analysis including subgroups, if applicable, and reporting accrual annually and results of analyses, as appropriate.
- ▶ **Guidelines and instructions for reviewers and Scientific Review Administrators (SRAs) were developed** to emphasize and clarify the need to review research proposals that are classified as NIH-defined Phase III clinical trials for both inclusion requirements and issues related to analyses by sex/gender and/or race/ethnicity. Instructions were developed for the proper documentation to include in summary statements to address adherence to these policies.

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

The PHS 398 Grant Application was significantly revised to provide additional instructions about the Women and Minorities Inclusion Policy and the revised form became mandatory as of May 10, 2005. These PHS 398 instructions about the Women and Minorities Inclusion Policy have also been included in the new federal application form SF-424 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.

Many of the training sessions are available electronically for all NIH staff, and the Office of Extramural Research (OER) has made available existing training materials on the Population tracking system website on the NIH Intranet. A training subcommittee of the full NIH Tracking and Inclusion committee has been established to develop new training documents and methods of training for NIH staff and the extramural research community. Further information regarding training initiatives since the 2000 GAO report is discussed in the background section of the Appendices (See Appendix A)

Communication and Outreach Efforts to the Scientific Community

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

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

Inclusion in NIH Clinical Research: What Investigators Need to Know!” was developed for NIH staff to assist them in working with the extramural community.

Monitoring Compliance: Extramural and Intramural Population Data Analysis

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

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

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

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

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

Format Changes for Reporting Race and Ethnicity Data

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

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

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

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

- the OLD FORM uses the 1977 OMB combined Race and Ethnicity Format, which has mutually exclusive categories, and allows Hispanics to be reported as either "Hispanic, Not White" or "White".
- the NEW FORM uses the 1997 OMB Race and Ethnicity Categories, with separate reporting for Ethnicity (Hispanic or Latino; Not Hispanic or Latino) and Race (Part A); in this format, an individual is classified both by Ethnic Category and by Race Category. Part B of the NEW FORM therefore provides a distribution of only "Hispanics or Latinos" by the five main Race categories. Since minority categories are defined to include both "Hispanic or Latino ethnicity" and non-white racial categories when providing summary totals of minorities, it is necessary to add "White Hispanics" and "Unknown/Other Hispanics" based on their ethnicity to the non-white racial categories.
- Hispanics are defined by country of origin, and may be identified as belonging to any one, or more than one, race category.

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

NEW FORM: Separate 1997 OMB Race/Ethnicity Categories		
Part A: Enrollment by RACE		
American Indian/Alaska Native		X
Asian		X
Black or African American		X
Hawaiian/Pacific Islander		X
White		
More Than One Race		X
Unknown/Other		
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
* Hispanic Totals Included in Part A		

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

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

DEFINITIONS:

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

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues

that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies;
(2) Epidemiologic and behavioral studies; and
(3) Outcomes research and health services research

NIH-Defined Phase III Clinical Study

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

Valid Analysis

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

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

Significant Difference

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

Domestic organization

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

Foreign institution

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

CONCLUSION AND CURRENT STATUS

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

References

1. Public Law 103-43. National Institutes of Health Revitalization Act of 1993, 42 USC 289 (a)(1).
2. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508-14513 (1994).
3. *Women's Health: NIH Has Increased Its Efforts to Include Women in Research* (GAO/HEHS-00-96, May, 2000).
4. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, NIH Guide for Grants and Contracts, Amended 2001.

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

1. NIH Office of Extramural Research Inclusion of Women and Minorities Policy Implementation Website: http://grants.nih.gov/grants/funding/women_min/women_min.htm
2. Revitalization Act of 1993, 42 USC 289 (a)(1): <http://grants.nih.gov/grants/guide/notice-files/not94-100.html>
3. 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>
4. Office of Research on Women's Health Website: <http://orwh.od.nih.gov/inclusion.html>

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

***Fiscal Year 2005 Summary Reports
11-year Trend Summary Reports***

Summary Report of NIH Inclusion Data

NIH AGGREGATE POPULATION DATA REPORTED IN FY2004 and FY2005

Data on inclusion is tabulated from human subject populations in NIH-defined Phase III clinical trials and other human subject research studies. NIH clinical research studies are determined in accordance with the NIH definition of clinical research to include, for example, non-intervention clinical research, clinical trials, epidemiologic studies, behavioral studies, and database studies.

Analysis of aggregate NIH data on inclusion for FY2004 and FY2005 document that substantial numbers of women and men, especially non-minority men, and minorities have been included as research subjects in NIH-defined Phase III clinical trials and other human subject research studies during these fiscal years. Because the data included in the tables are aggregate data from across NIH, it does provide documentation of the tracking and inclusion across the NIH, and some degree of analysis of the data. But caution should be utilized in not over-interpreting the figures that are provided. The NIH Tracking and Inclusion committee has provided for the reader's interest, conclusions that can be reasonably drawn from the data.

Previous inclusion reports and aggregate enrollment figures for women, men and minority groups for FY1994 to the present can be found on the ORWH website at <http://orwh.od.nih.gov/inclusion.html>. For this report, the FY2004 and FY2005 data tables have been reformatted and some tables may vary slightly or differ from prior reported summary data in an effort to better clarify reporting.

NIH CLINICAL RESEARCH: Fiscal Years 2004 and 2005

In FY2004 there were 14,512 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,125 protocols reported human subject participation as noted in this report's trend summary tables. Of these, 96.4% were domestic protocols and 3.6% were foreign protocols. Approximately 18.9 million participants were enrolled in extramural and intramural research protocols of which 75.9% were domestic participants and 24.1% were foreign participants. Of the 18.9 million participants, 57.5% were women, 40.9% were men and 1.5% did not provide sex identification. Further, 35.8% of the total participants, and 24.1% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (*Table 6*)

Correspondingly, in FY2005, there were 14,798 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,233 protocols reported human subject participation. Of these, 96.4% were domestic protocols and 3.6% were foreign protocols. Approximately 15.7 million participants were enrolled in extramural and intramural research protocols of which 80.6% were domestic participants and 19.4% were foreign participants. Of the 15.7 million participants, 60.4% were women, 37.8% were men and 1.8% did not provide sex identification. Further, 39.7% of the total participants, and 27.4% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (*Table 1*)

While the number of participants in all extramural and intramural clinical research decreased (18.9M in FY2004 and 15.7M in FY2005), there was no significant change in the ratio of women and men (57.5%F and 40.9%M in FY2004; and 60.4%F and 37.8%M in FY2005). Two large studies involving approximately 3M participants, that ended in FY2004 and therefore were not included in the FY2005 figures, accounted for the decreased number of participants reported.

NIH Defined Phase III Clinical Research: FY2004 and FY2005

In FY2004 there were 692 extramural and intramural Phase III clinical research protocols, of which 576 protocols reported human subject participation as noted in this report's trend summary tables. Of these, 94.7% were domestic protocols and 5.3% were foreign protocols. Approximately 516,360 participants were enrolled in extramural and intramural Phase III research protocols of which 90.5% were domestic participants and 9.5% were foreign participants. Of the 516,360 participants, 55.5% were women, 44.2% were men and 0.2% did not provide sex identification. Further, 27% of the total participants, and 25.4% of Domestic-only participants, in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (*Table 7*)

According to the trend summaries in this report, of the 296 extramural and intramural Phase III research protocols that report following the 1977 OMB standards in FY2004, minority representation was highest for Blacks (not Hispanic) at 12.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 8.7%, Asian/Pacific Islanders were 5% and Whites (not Hispanic) 70.2% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*Table 7*)

Furthermore, in FY 2004, there were 277 extramural and intramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 26.2% and lowest for Hawaiian/Pacific Islanders 0.4%. Asians represented 2.6%, American Indian/Alaska Natives 0.8% and Whites 64% of participants. Participants identifying as *More Than One Race* were 2.6% of the total number of participants. In addition, 3.4% did not identify a race category. Of the 277 extramural and intramural Phase III research protocols designating an ethnicity in FY2004, 87.3 % of total participants identified as "Not Hispanic", 8.0 % of the total participants identified as "Hispanic or Latino", and 4.7% of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (*Table 7*)

Correspondingly, in FY2005, there were 665 extramural and intramural Phase III clinical research protocols, of which 547 protocols reported human subject participation. Of these, 94.5% were domestic protocols and 5.5% were foreign protocols. Approximately 493,000 participants were enrolled in extramural and intramural Phase III research protocols of which 88.8% were domestic participants and 11.2% were foreign participants. Of the 493,000 participants, 59% were women, 40% were men and 1% did not provide sex identification. Further, 31.3% of the total participants, and 25.1% of the Domestic-only participants, in Phase III clinical research were reported as minorities following the 1997 OMB categories for race and ethnicity. (*Table 3*)

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

Moreover, in FY2005, there were 337 extramural and intramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 28.5% and lowest for Hawaiian/Pacific Islanders 0.3%. Asians represented 5.2%, American Indian/Alaska Natives 1.2% and Whites 57.3% of participants. Participants identifying as *More Than One Race* were 1.7% of the total number of participants. In addition, 5.8% did not identify a race category. Of the 337 extramural and intramural

Phase III research protocols designating an ethnicity in FY2005, 88.6 % of total participants identified as “Not Hispanic”, 5.9% of the total participants identified as “Hispanic or Latino” and 5.5% of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (*Table 7*)

While the number of participants in Phase III extramural and intramural clinical research slightly decreased (516,360 in FY2004 and 493,000 in FY2005), there was no significant change in the ratio of women and men (55.5% F and 44.2% M in FY2004; and 59% F and 40% M in FY2005).

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

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2004 and 2005

In FY2004 there were 12,795 extramural clinical research protocols, including Phase III and other clinical studies, of which 8,734 protocols reported human subject participation as noted in this report’s trend summary tables. Approximately 16.9 million participants were enrolled in extramural research protocols of which 58.6% were women, 39.8% were men and 1.6% did not provide sex identification. (*Table 11*)

Correspondingly, in FY2005, there were 13,003 extramural clinical research protocols, including Phase III and other clinical studies, of which 8,763 protocols reported human subject participation. Of these, 82.7% were domestic protocols and 2.9% were foreign protocols. Approximately 13.8 million participants were enrolled in extramural research protocols of which 70.2% of the total enrollment is domestic participants and 17.5% of the total enrollment is foreign participants. Of the 13.8 million participants, 62.1% were women, 36.1% were men and 1.9% did not provide sex identification. Further, 42.3% of the total participants were reported as minorities following the OMB categories for race and ethnicity. (*Table 2 and Table 3A*)

While the number of participants in all extramural clinical research decreased (16.8 million in FY2004 and 13.8 million in FY2005), there was no significant change in the ratio of women and men (58.6% F and 39.8% M in FY2004; and 62% F and 36% M in FY2005). However, when sex-specific studies were excluded the proportions of women and men in all extramural clinical research were proportional to the percentages of the general population. Two large studies involving approximately 3M participants, that ended in FY2004 and therefore were not included in the FY2005 figures, accounted for the decreased number of participants reported.

NIH Defined Phase III Extramural Clinical Research: FY2004 and FY2005

In FY2004 there were 650 extramural Phase III clinical research protocols, of which 500 protocols reported human subject participation as noted in this report’s trend summary tables. Approximately 482,325 participants were enrolled in extramural Phase III research protocols of which 56% were women, 44% were men and 0.02% did not provide sex identification. (*Table C04 and Table 15 from the 2005 report*)

Of the 273 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7%, Asian/Pacific Islanders were 1.9% and Whites (not Hispanic) 76% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*Table 15 from the 2005 report*)

According to trend summaries in this report, in FY 2004, there were 266 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 24.3% and lowest for

Hawaiian/Pacific Islanders 0.3%. Asians represented 2.46%, American Indian/Alaska Natives 0.8% and Whites 66.5% of participants. Participants identifying as *More Than One Race* were 2.6% of the total number of participants. In addition, 3.06 % did not identify a race category. Of the 266 extramural Phase III research protocols designating an ethnicity in FY 2004, 86.38 % of total participants identified as “Not Hispanic”, 8.53 % of the total participants identified as “Hispanic or Latino”, and 5.08 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (*Table 15 from the 2005 report*)

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

Of the 192 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 18 and lowest for American Indian/Alaska Natives at 0.38%. Hispanics represented approximately 7.2%, Asian/Pacific Islanders were 1.81% and Whites (not Hispanic) 76% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards. (*Appendix Table 5A*)

Furthermore, in FY 2005, there were 319 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 30.00 % and lowest for Hawaiian/Pacific Islanders 0.28%. Asians represented 5.44%, American Indian/Alaska Natives 1.30% and Whites 55.75% of participants. Participants identifying as *More Than One Race* were 1.56% of the total number of participants. In addition, 5.66 % did not identify a race category. Of the 319 extramural Phase III research protocols designating an ethnicity in FY2005, 88.7 % of total participants identified as “Not Hispanic”, 5.98 % of the total participants identified as “Hispanic or Latino”, and 5.32 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (*Appendix Table 5A*)

While the number of participants in Phase III extramural clinical research protocols slightly increased (500 in FY2004 and 511 in FY2005), there was no significant change in the ratio of women and men (56%F and 44%M in FY2004; and 59.5%F and 39.5%M in FY2005).

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2004 and 2005

Substantial numbers of women and minorities were included in NIH intramural studies in FY 2004 and FY2005.

In FY2004 there were 1,717 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,391 protocols reported human subject participation. Approximately 1.94 million participants were enrolled in intramural research protocols of which 48.4% were women, 50.1% were men and 1.5% did not provide sex identification. (*Table C04 and Table 11 from the 2005 report*)

In FY 2004, approximately 1.9 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 951 intramural research protocols that report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 10.5% and lowest for American Indian/Alaska Natives at 0.9%. Blacks (not-Hispanic) represented 5.6%,

For 440 intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2004, the largest racial minority group was Blacks at 9.14% and the smallest racial minority group was Hawaiian/Pacific Islanders at .01%. Asians represented 4.2%, American Indian/Alaska Natives 1.1% and Whites 78.7% of participants in all intramural clinical research. Approximately 0.2% of participants reported *More Than One Race* as their racial category. In addition, 6.70 % did not identify a race category. Of the 440 intramural research protocols following the current 1997 OMB standards designating an ethnicity in FY2004, 95.7 % of total participants identified as “Not Hispanic”, 2.83 % of the total participants identified as “Hispanic or Latino”, and 1.48 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (*Table 19 from the 2005 report*)

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

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

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

There was no significant change in the ratio of women and men or the number of participants in all intramural clinical research.

NIH Defined Phase III Intramural Clinical Research: FY2004 and FY2005

In FY2004 there were 37 intramural Phase III clinical research protocols reporting human subject participation. Approximately 34,035 participants were enrolled in intramural Phase III research protocols of which 50.2% were women, 49.8% were men and 0% did not provide sex identification. (*Table 23 from the 2005 report*)

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

There was no significant change in the ratio of women and men or the number of participants in Phase III intramural clinical research.

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY1995 – FY2005

The following section is a new addition to the Annual Comprehensive report. Tables 5-11 provide trend data on the collection and reporting of human subject participation in NIH funded clinical research, which includes Phase III clinical studies; trend data are also provided in terms of foreign and domestic participation. Trend data 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 5 is an 11-year summary report showing a steady increase in protocols and enrollment data collected. The number of protocols with enrollment increased from 3,188 in FY2005 to 10,233 in FY2005 – a 3.2 fold increase. Reported enrollment increased from approximately 1 million (FY1995) to 15.7 million (FY2005) – a 15.4 fold increase; minority enrollment increased from 0.37 million (FY1995) to 6.2 million (FY2005) – a 16.7 increase in minority representation in NIH clinical research. Over the last three to five years, the total number of protocols reported with enrollment data has leveled off at about 10,000 protocols per year.

With the deployment of a new population tracking system in 2002 and the requirement to report data using a new format, NIH was able to report domestic and foreign data in a better way. Thus, trend data are now available for domestic and foreign protocols and participation beginning in FY2002. Domestic enrollment increased from 10.2 million (FY1995) to 12.7 million (FY2005) – a 1.2 fold increase. Foreign enrollment increased from 0.9 million (FY1995) to 3 million (FY2005) – a 3.2 fold increase. Overall, the total enrollment has increased with domestic participation averaging between 80-91% and foreign participation averaging between 8.5-24%. In FY2005, domestic and foreign enrollment was 80.6% and 19.4% respectively.

Table 6 is a summary report of all extramural and intramural clinical research by sex/gender and minority representation following the old and new data formats for domestic and foreign studies. The report demonstrates that female participation in all extramural and intramural research generally averaged between 52% and 64%, male participation in all extramural and intramural research averaged between 36% and 45%. Overall minority participation in all extramural and intramural clinical research averaged between 31% and 40%. Table 6E provides a comparison of domestic and foreign participation between FY2002 and FY2005. The vast majority of protocols are domestic (94%-96%) of the total clinical research protocols. While the number of foreign protocols has increased, they incorporate only about 4%-6% of the total clinical research protocols with enrollment. Table 6F shows domestic and foreign enrollment for the five-year period. Domestic minority enrollment varied between 24.1% and 27.4% of total domestic participation, while foreign minority enrollment varied between 82.2% and 90.9% of total foreign participation.

Table 7 is a summary report of NIH-funded Phase III extramural and intramural clinical research by sex/gender, minority representation following the old and new data reporting formats for domestic and foreign studies. The report demonstrates that female participation in NIH funded Phase III extramural and intramural clinical research generally averaged between 54% and 75% and male participation in NIH-funded Phase III extramural and intramural clinical research averaged between 28% and 44%. Overall minority participation in NIH-funded Phase III extramural and intramural clinical research averaged between 2% and 31%. Table 7E provides a comparison of domestic and foreign participation between FY2002 and FY2005. The vast majority of protocols are domestic (75% and 96%) of the total clinical research protocols. While the number of foreign protocols has increased, they incorporate only about 4%-24% of the total clinical research protocols with enrollment. Table 7F shows domestic and foreign enrollment for the five-year period. Domestic minority enrollment varied between 20.9% and 25.4% of total domestic participation, while foreign minority enrollment in NIH-funded Phase III clinical research

varied between 48.4% and 80.4% of total foreign participation. Comparing both domestic and foreign enrollment over the five year period shows that the small percentage of foreign protocols (5.5%) account for a significant proportion (28.7%) of the total minority enrollment.

Tables 8-11 provide summary reports of domestic and foreign participation for NIH funded clinical research and NIH-funded Phase III clinical research. For extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation averaged 62% while male participation averaged 36%. (*Table 8*) For NIH-funded Phase III extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation averaged 57% while male participation averaged 42%. (*Table 9*) For all extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 39% to 58% while male participation varied from 40% to 60%. (*Table 10*) For NIH-funded Phase III extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 47% to 57% while male participation varied from 42% to 53%. (*Table 11*)

Table 1. Summary of NIH Clinical Research Reported In FY2005 :Total Number of Protocols and Enrollment By Sex, and Domestic versus Foreign Protocols

	Total All Clinical Studies*	Domestic	%	Foreign	%
1A. PROTOCOLS REPORTED					
Protocols with Enrollment	10,233	9,862	96.4%	371	3.6%
%	69.2%	69.4%		62.7%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,565	4,344	95.2%	221	4.8%
	30.8%	30.6%		37.3%	
Total Number of Protocols	14,798	14,206	96.0%	592	4.0%
%	100.0%	100.0%		100.0%	

Table 1A Comments:

Total Number of Protocols

1. The total number of protocols reported in the NIH database in FY2005 was 14,798; of these, 10,233(69.2%) reported subject enrollment.
2. Subsequent Tables reporting "Enrollment Reported" are based on the 10,233 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 (14,206; 96.0%); of these, 9,862 (69.4%) 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 All Clinical Studies*	Domestic	%	Foreign	%
1B. ENROLLMENT REPORTED					
Females Enrolled	9,503,922	7,887,209	83.0%	1,616,713	17.0%
%	60.4%	62.3%		53.0%	
Males Enrolled	5,941,907	4,515,242	76.0%	1,426,665	24.0%
%	37.8%	35.6%		46.7%	
Sex of Subjects is Unknown	276,923	267,407	96.6%	9,516	3.4%
%	1.8%	2.1%		0.3%	
Total Subjects Enrolled	15,722,752	12,669,858	80.6%	3,052,894	19.4%
%	100.0%	100.0%		100.0%	

Table 1B Comments:

Total Enrollment Reported

1. The total "Enrollment Reported" in the NIH database in FY2005 was 15, 722, 752 subjects in 10,233 protocols with enrollment.
2. Females made up 60.4% (9.5M) of the total subjects enrolled, while Males made up 37.8%(5.9M), with 1.8% (.277M) unknown.

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 12,669,858 (80.6%).
5. Females made up 62.3%(7.9M) of the domestic subjects enrolled, while Males made up 35.6%(4.5M), with 2.1%(.267M) unknown.

	Total All Clinical Studies*	Domestic	%	Foreign	%
1C. MINORITY ENROLLMENT REPORTED					
Minority Total**	6,245,436	3,468,864	55.5%	2,776,572	44.5%
	39.7%	27.4%		90.9%	

Table 1C Comments.

1. Minorities made up 39.7% of total subjects enrolled.
2. Minorities made up 27.4%(3.47M) of the Domestic Enrollment.
3. The Total Minority Enrollment was made up of 55.5% Domestic and 44.5% Foreign enrollment. The small percentage of foreign protocols account for a significant proportion (44.5%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

* 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.

Table 2: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2005: Number of Sex Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

		Domestic				Foreign			
	Total All Clinical Studies	Extramural	%	Intramural	%	Extramural	%	Intramural	%
2A. PROTOCOLS REPORTED									
Number of Protocols reporting females only	1,326	1,156	87.2%	124	9.4%	40	3.0%	6	0.5%
%	9.0%	9.2%		7.3%		8.0%		6.6%	
Number of Protocols reporting males only	559	450	80.5%	97	17.4%	9	1.6%	3	0.5%
%	3.8%	3.6%		5.7%		1.8%		3.3%	
Number of Other Protocols with Enrollment (excluding females only and males only protocols)	8,348	6,857	82.1%	1,178	14.1%	251	3.0%	62	0.7%
%	56.4%	54.8%		69.1%		50.1%		68.1%	
Total Number of Protocols with Enrollment	10,233	8,463	82.7%	1,399	13.7%	300	2.9%	71	0.7%
%	69.2%	68%		82.1%		59.9%		78.0%	
Number of Protocols with zero enrollment. Enrollment data has not yet been submitted.	4,565	4,039	88.5%	305	6.7%	201	4.4%	20	0.4%
%	30.8%	32.3%		17.9%		40.1%		22.0%	
Total Number of Protocols	14,798	12,502	84.5%	1,704	11.5%	501	3.4%	91	0.6%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

Table 2A Comments

Total Number of Protocols with Enrollment

1. Female Only: There were 1,326 protocols reporting females only, representing 13.0 %(1,326/10,233) of protocols with enrollment, and 9.0% of the Total Number of Protocols.

90.2% were Extramural projects(1,156+40); 9.8% were NIH intramural projects(124+6)

96.6% were Domestic protocols(1,156+124); 0.4% were Foreign protocols(40+6).

2. Male Only: There were 559 protocols reporting males only, representing 5.5%(559/10,233) of protocols with enrollment, and 3.8% of the Total Number of Protocols.

85.1% were Extramural projects(450+9); 14.9% were NIH intramural projects(97+3)

97.8% were Domestic protocols(450+97); 0.2% were Foreign protocols(9+3).

3. Other Protocols: There were 8,348 protocols with enrollment excluding female only and male only protocols, representing 81.6%(8,348/10,233) of protocols with enrollment, and 56.4 % of the Total Number of Protocols.

82.1% were Extramural projects(6,857+251); 17.9% were NIH intramural projects(1,178+62)

96.2% were Domestic protocols(6,857+1,178); 3.8% were Foreign protocols(251+62).

4. Approximately 70% of the total number of protocols reported enrollment; the remaining protocols have not yet submitted their first annual enrollment data.

		Domestic				Foreign			
	Total All Clinical Studies	Extramural	%	Intramural	%	Extramural	%	Intramural	%
2B. ENROLLMENT REPORTED									
In Protocols reporting females only	3,469,692	3,073,956	88.6%	166,709	4.8%	130,092	3.7%	98,938	2.9%
%	22.1%	27.9%		10.2%		4.7%		32.8%	
In Protocols reporting males only	317,697	241,871	76.1%	25,513	8.0%	25,218	7.9%	25,120	7.9%
%	2.0%	2.2%		1.6%		0.9%		8.3%	
In Protocols excluding female-only and men-only enrollment protocols	11,935,363	7,714,690	64.6%	1,447,119	12.1%	2,596,372	21.8%	177,154	1.5%
%	75.9%	69.9%		88.3%		94.4%		58.8%	
Enrollment Totals for all studies	15,722,752	11,030,517	70.2%	1,639,341	10.4%	2,751,682	17.5%	301,212	1.9%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

Table 2B Comments

Total Enrollment

1. In Female Only Protocols: There were approximately 3.47M females, representing 22.1% of total enrollment.

92.3% (3.20M) were in Extramural projects; 7.7% (.266M) were in NIH intramural projects

93.4% (3.24M) were in Domestic protocols; 6.6% (.229M) were in Foreign protocols.

2. In Male Only Protocols: There were approximately 317,697 males, representing 2.0% of total enrollment.

84.1% (267,089) were in Extramural projects; 15.9%(50,633) were in NIH intramural projects

84.2% (267,384) were in Domestic protocols; 15.8% (50,338) were in Foreign protocols.

3. In Other Protocols: There were approximately 11,935,363 subjects, representing 75.9% of total enrollment

86.4% (10.31M) were in Extramural projects;13.6% (1.62M) were in NIH intramural projects

76.8% (9.16M) were in Domestic protocols; 23.2%(2.77M) were in Foreign protocols

		Domestic				Foreign			
		Extramural	%	Intramural	%	Extramural	%	Intramural	%
2C. MINORITY ENROLLMENT REPORTED**									
Minority Totals for all studies	6,245,436	3,235,752	51.8%	233,112	3.7%	2,597,525	41.6%	179,047	2.9%
%	39.7%	29.3%		14.2%		94.4%		59.4%	

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

Table 2C. Comments

Minority Enrollment

1. Total Minority Enrollment was 39.7% (6.25M) of Total Enrollment (15.72M).

Total Minority enrollment, **Extramural** protocols(5.83M), was 37.1% of Total Enrollment(15.72M) and 93.3% of Total Minority Enrollment (6.25M)

Total Minority enrollment, **Intramural** Projects(412,159), was 2.6% of Total Enrollment (15.72M) and 6.6% of Total Minority Enrollment (6.25M)

2. Total Minority Enrollment, Domestic only(3.47M), was 27.4% of total Domestic Enrollment (12.67M) and 55.5% of Total Minority Enrollment (6.25M)

3. Total Minority Enrollment, Foreign only (2.78M), was 91.1% of Total Foreign Enrollment (3.05M) and 44.5% of Total Minority Enrollment (6.25M)

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2005: Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

3A. PROTOCOLS REPORTED	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Protocols with Enrollment	547	517	94.5%	30	5.5%
%	82.3%	83.7%		63.8%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	118	101	85.6%	17	14.4%
	17.7%	16.3%		36.2%	
Total Number of Protocols	665	618	92.9%	47	7.1%
%	100.0%	100.0%		100.0%	

Table 3A Comments:

Total Number of Protocols

1. The total number of NIH defined Phase III Clinical protocols reported in the NIH database in FY2005 was 665; of these, 547(82.3%) reported subject enrollment.
2. Subsequent Tables reporting "Enrollment Reported" are based on the 665 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 (618; 92.9%); of these 517(83.7%) reported domestic subject enrollment.
5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

3B. ENROLLMENT REPORTED	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Females Enrolled	290,977	261,589	89.9%	29,388	10.1%
%	59.0%	59.7%		53.3%	
Males Enrolled	197,300	174,137	88.3%	23,163	11.7%
%	40.0%	39.8%		42.0%	
Sex of Subjects is Unknown	4,723	2,176	46.1%	2,547	53.9%
%	1.0%	0.5%		4.6%	
Total Subjects Enrolled	493,000	437,902	88.8%	55,098	11.2%
%	100.0%	100.0%		100.0%	

Table 3B Comments:

Total Enrollment Reported

1. The total "Enrollment Reported" in NIH Defined Phase III Protocols in the NIH database in FY2005 was 493,300 subjects in 547 protocols with enrollment.
2. Females made up 59.0% (290,977) of the total subjects enrolled, while Males made up 40.0%(197,300), with 1.0%(4,723) unknown.

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 437,902(88.8%).
5. Females made up 59.7%(261,589) of the domestic subjects enrolled, while Males made up 39.8%(174,137), with 0.5%(2,176) unknown.

3C. MINORITY ENROLLMENT REPORTED**	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Minority Total for all Phase III studies	154,191	109,910	71.3%	44,281	28.7%
	31.3%	25.1%		80.4%	

Table 3C Comments. Minority Enrollment Reported.

1. Minorities made up 31.3% of total subjects enrolled.
2. Minorities made up 25.1%(109,910) of the Domestic Enrollment (437,902).
3. The Total Minority Enrollment was made up of 71.3% Domestic and 28.7% Foreign enrollment.

* 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.

Table 4. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2005: Number of Sex Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

		Domestic				Foreign			
	Total of Phase III Clinical Trials*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
4A. PROTOCOLS REPORTED									
Protocols reporting women only	127	120	94.5%	1	0.8%	6	4.7%	0	0.0%
%	19.1%	20.7%		2.6%		14.3%		0.0%	
Protocols reporting men only	34	29	85.3%	4	11.8%	1	2.9%	0	0.0%
%	5.1%	5.0%		10.3%		2.4%		0.0%	
Other Protocols with Enrollment (excluding women only and men only protocols)	386	335	86.8%	28	7.3%	20	5.2%	3	0.8%
%	58.0%	57.9%		71.8%		47.6%		60.0%	
Total Number of Protocols with Enrollment	547	484	88.5%	33	6.0%	27	4.9%	3	0.5%
%	82.3%	84%		84.6%		64.3%		60.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.	118	95	80.5%	6	5.1%	15	12.7%	2	1.7%
%	17.7%	16.4%		15.4%		35.7%		40.0%	
Total Number of Phase III Protocols	665	579	87.1%	39	5.9%	42	6.3%	5	0.8%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

Table 4A Comments

Total Number of Protocols with Enrollment

- Female Only:** There were 127 protocols reporting females only, representing 23.20 %(127/547) of protocols with enrollment, and 19.1% of the Total Number of Protocols.
99.2% were Extramural projects(126); 0.8% were NIH intramural projects(1)
95.3% were Domestic protocols(121); 4.7% were Foreign protocols(6).
- Male Only:** There were 34 protocols reporting males only, representing 6.2%(34/547) of protocols with enrollment, and 5.1% of the Total Number of Protocols.
88.2% were Extramural projects(30); 11.8% were NIH intramural projects(4)
97.0% were Domestic protocols(33); 3.0% were Foreign protocols(1).
- Other Protocols:** There were 386 protocols with enrollment excluding female only and male only protocols, representing 70.6%(386/547) of protocols with enrollment, and 58.0 % of the Total Number of Protocols.
92.0% were Extramural projects(355); 8.0% were NIH intramural projects(31)
94.0% were Domestic protocols(363); 6.0% were Foreign protocols(23).

		Domestic				Foreign			
	Total of Phase III Clinical Trials*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
4B. ENROLLMENT REPORTED									
Protocols reporting women only	157,329	149,953	95.3%	1	0.0%	7,375	4.7%	0	0.0%
%	31.9%	35.4%		0.0%		17.5%		0.0%	
Protocols reporting men only	56,191	54,050	96.2%	46	0.1%	2,095	3.7%	0	0.0%
%	11.4%	12.8%		0.3%		5.0%		0.0%	
Protocols excluding female-only and men-only enrollment protocols	279,480	219,775	78.6%	14,077	5.0%	32,708	11.7%	12,920	4.6%
%	56.7%	51.9%		99.7%		77.5%		100.0%	
Total Subjects Enrolled	493,000	423,778	86.0%	14,124	2.86%	42,178	8.56%	12,920	2.6%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

Table 4B Comments

Total Enrollment

- In Female Only Protocols:** There were approximately 157,329 females, representing 31.9% of total enrollment.
99.9% (157,328)were in Extramural projects; .01% (1) were in NIH intramural projects
95.3% (149,954) were in Domestic protocols; 4.7% (7,375) were in Foreign protocols.
- In Male Only Protocols:** There were approximately 56,191 males, representing 11.4% of total enrollment.
99.9% (56,145) were in Extramural projects; 0.1%(46) were in NIH intramural projects
96.3% (54,096) were in Domestic protocols; 3.7% (2,095) were in Foreign protocols.
- In Other Protocols:** There were approximately 279,480 subjects, representing 56.7% of total enrollment
90.3% (252,483) were in Extramural projects; 9.7% (26,997) were in NIH intramural projects
83.7% (233,852) were in Domestic protocols; 16.3%(45,628) were in Foreign protocols

		Domestic				Foreign			
	Total of Phase III Clinical Trials*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
4C. MINORITY ENROLLMENT REPORTED**									
Minority Total for all Phase III studies	154,191	107,513	69.7%	2,397	1.6%	31,943	20.7%	12,338	8.0%
%	31.3%	25.4%		17.0%		75.7%		95.5%	

Table 4C. Comments

Minority Enrollment

- Total Minority Enrollment** was 31.3% (154,191) of Total Enrollment (493,000).
Total Minority enrollment, **Extramural** protocols(139,456), was 28.3% of Total Enrollment(493,000) and 90.4% of Total Minority Enrollment (154,191)
Total Minority enrollment, **Intramural** Projects(14,735), was 3.0% of Total Enrollment (493,000) and 9.6% of Total Minority Enrollment (154,191)
- Total Minority Enrollment, **Domestic only(109,910)**, was 23.6% of total Domestic Enrollment (465,956) and 71.3% of Total Minority Enrollment (154,191)
- Total Minority Enrollment, **Foreign** only(44,281), was 80.3% of Total Foreign Enrollment (55,098) and 28.7% of Total Minority Enrollment (154,191)

* 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.

Table 5. Eleven Year Trends for Protocol and Enrollment Data: 1995-2005*

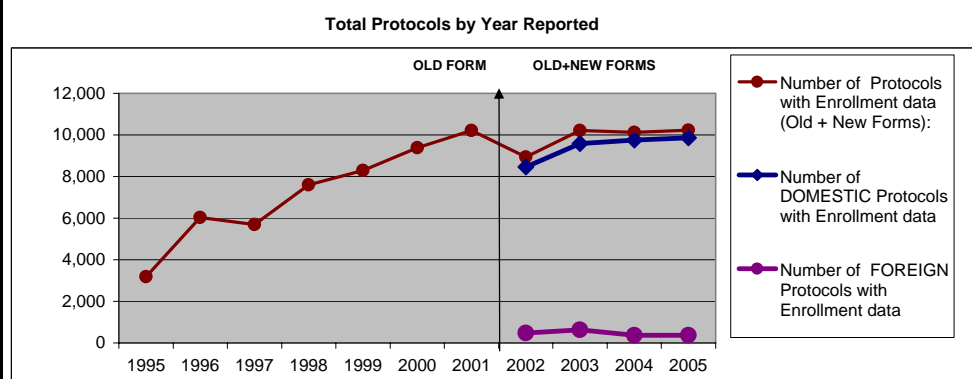
5A. Eleven Year Increases in Protocols and Enrollment Data				
FY Reported	1995		2005	Relative Increase, 2005 / 1995
Total Protocols with enrollment	3,188		10,233	3.2
Total Enrollment	1,021,493		15,722,752	15.4
Total Minorities	374,433		6,245,436	16.7
% of Minority	36.7%		39.7%	1.1
FY Reported	2002		2005	Relative Increase, 2005 / 2002
Total DOMESTIC Enrollment data	10,192,401		12,669,858	1.2
Total FOREIGN Enrollment	946,083		3,052,894	3.2

Table 5A Comments:

1. There was a 3.2 fold increase in protocols with enrollment reported from 1995 to 2005, from 3,188 protocols to 10,233 protocols.
2. There was a 15.4 fold increase in enrollment reported from 1995 to 2005, from approximately 1.0M to 15.7 M.
3. There was a 16.7 fold increase in minority enrollment from 1995 to 2005, from approximately 0.37M to 6.2 M.
4. Domestic and Foreign data were reported for FY 2002-2005, and showed 1.2 fold increase in domestic enrollment (from 10.2M to 12.7M) and a 3.2 fold increase in foreign enrollment (from 0.95M to 3.0M).

5B. Eleven Year Summary of Total Protocols Reported in FY 1995-2005

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%	



Note: The arrow in the graph indicates that the old Form was used until 2001 reports, and both the OLD and NEW FORMS were used for 2002-2005 reports.

* Protocol Form. 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 2002-2005, data have been reported using both Old and New Forms. See Appendix table "Minority Data Definitions" for details.

Table 5B Comments:

1. Table 5B and 5B Graph provide the number of OLD and NEW protocols year by year (1995-2005) and the distribution between domestic and foreign protocols for years 2002-2005.
2. The total number of protocols reported with enrollment have leveled off at about 10,000 over the last 3-5 years.
3. The vast majority of protocols were for domestic studies for 2002-2005, increasing slightly from 94.6% to 96.4% of protocols.

5C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2005

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%

Percent Comparison of Domestic and Foreign Enrollment

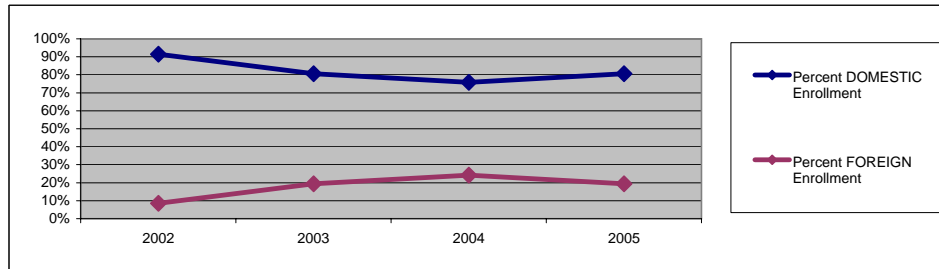


Table 5C Comments:

1. Overall total enrollment has increased, as well as domestic and foreign enrollment during the last four years. The percentage of domestic enrollment has decreased to approximately 80% as the foreign enrollment has increased to approximately 20%.

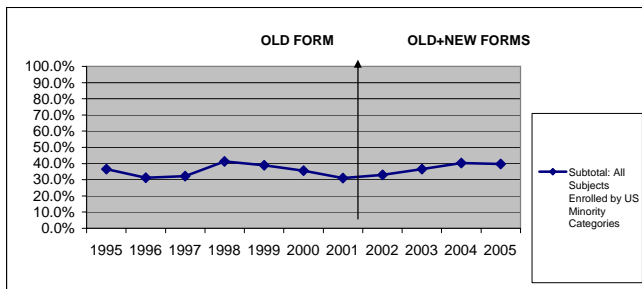
***NOTE:** Trend data varies over time because the data for each year represent the net total of data resulting from:(1) studies continuing from the prior year; (2) the addition of new studies reported; (3) and the subtraction of studies that are no longer reported.

Table 6. Eleven Year Minority Trend Summary of NIH Extramural and Intramural Clinical Research Reported in FY1995-2005: Enrollment by Race and Ethnicity

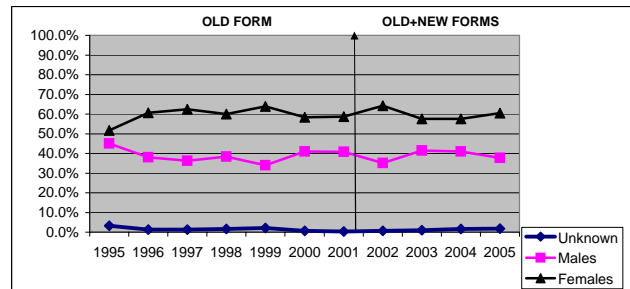
6A. ELEVEN YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER AND MINORITY CATEGORIES IN ALL PROTOCOLS (Old + New Forms)

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%	100.0%	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%	

Total Enrollment by Year Reported



Sex/Gender Enrollment by Year Reported



Note: The arrow in the graphs indicates that the old Form was used until 2001 reports, and both the OLD and NEW FORMS were used for 2002-2005 reports.

Table 6A Comments:

1. Table 6A summarizes enrollment by sex/gender and minority race/ethnicity categories for the eleven year reporting period (1995-2005). The data are compiled from Tables 6B, 6C and 6D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 6B) and the NEW Enrollment Form (Tables 6C and 6D).
2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

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

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 (below the dark row) are from the new Population Tracking System that was deployed with data reported in FY 2002, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

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

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

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

ORIENTATION TO TABLES 6C and 6D.

1. The New Form consists of Parts A and B (Tables 6C and 6D) for reporting years 2002-2005. This Form is provided as part of the annual progress report
2. Table 6C displays the New Form Part A for reporting separate race and ethnicity data
3. Table 6D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the "Hispanic or Latino" column in Part A.

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

Total of All Subjects by Race										Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total*	Not Hispanic	Hispanic or Latino**	Unknown /Not Reported	Total*
2002	2001	77,734	354,049	547,776	21,636	2,651,541	30,955	720,362	4,404,053	3,071,952	292,429	1,039,672	4,404,053
	%	1.8%	8.0%	12.4%	0.5%	60.2%	0.7%	16.4%	100.0%	69.8%	6.6%	23.6%	100.0%
2003	2002	63,544	2,138,002	960,090	37,569	5,415,710	99,462	1,012,622	9,726,999	8,162,259	611,641	953,099	9,726,999
	%	0.7%	22.0%	9.9%	0.4%	55.7%	1.0%	10.4%	100.0%	83.9%	6.3%	9.8%	100.0%
2004	2003	98,047	4,345,396	1,379,857	54,452	8,065,069	186,241	1,381,250	15,510,312	13,168,842	756,339	1,585,131	15,510,312
	%	0.6%	28.0%	8.9%	0.4%	52.0%	1.2%	8.9%	100.0%	84.9%	4.9%	10.2%	100.0%
2005	2004	292,215	3,046,370	1,358,262	53,286	7,672,890	182,953	1,105,722	13,711,698	11,804,164	773,939	1,133,595	13,711,698
	%	2.1%	22.2%	9.9%	0.4%	56.0%	1.3%	8.1%	100.0%	86.1%	5.6%	8.3%	100.0%

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

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown/Other	Total Hispanic or Latino**	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Protocols with Enrollment data (New Form):
2002	2001	4,867	1,305	13,066	101	159,252	7390	106,448	292,429	1,297,850	2,758
	%	1.7%	0.4%	4.5%	0.0%	54.5%	2.5%	36.4%	100.0%	29.5%	
2003	2002	5,400	1,953	14,566	679	350,439	28,088	210,516	611,641	3,859,622	5,313
	%	0.9%	0.3%	2.4%	0.1%	57.3%	4.6%	34.4%	100.0%	39.7%	
2004	2003	6,408	5,040	25,276	2,037	361,112	62,909	293,557	756,339	6,718,662	7,343
	%	0.8%	0.7%	3.3%	0.3%	47.7%	8.3%	38.8%	100.0%	43.3%	
2005	2004	22,739	7,816	19,446	1,981	388,874	51,166	281,916	773,938	5,603,876	8,447
	%	2.9%	1.0%	2.5%	0.3%	50.2%	6.6%	36.4%	100.0%	40.9%	

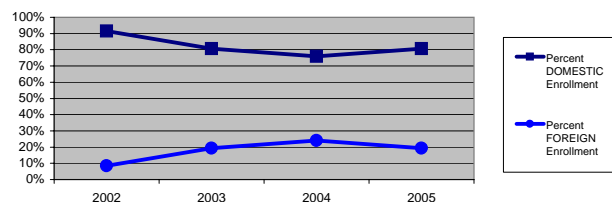
* These totals must agree.

**These totals must agree.

6E. Comparison of Domestic and Foreign Enrollment and Protocols with Total Enrollment for the period FY2002-2005

ENROLLMENT							PROTOCOLS				
FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC Enrollment	Percent DOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGN Enrollment	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols	Percent Domestic Protocols	Number of FOREIGN Protocols	Percent Foreign Protocols
2002	2001	11,138,484	10,192,401	91.5%	946,083	8.5%	8,945	8,463	94.6%	482	5.4%
2003	2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%	10,216	9,578	93.8%	638	6.2%
2004	2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%	10,125	9,760	96.4%	365	3.6%
2005	2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%	10,233	9,862	96.4%	371	3.6%

Percentage of Domestic and Foreign Enrollment



Number of Domestic and Foreign protocols

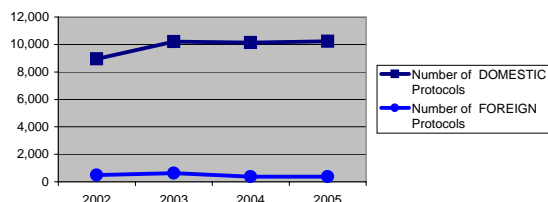


Table 6 E Comments:

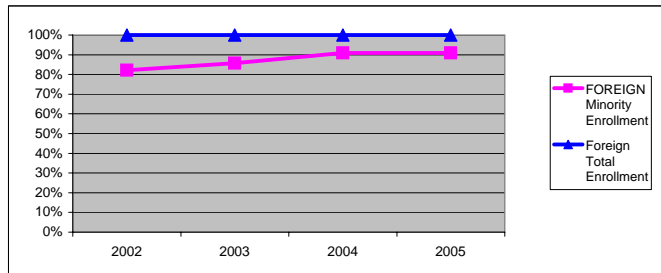
1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2005.
2. The Domestic enrollment decreased to approximately 80%, while the Foreign enrollment increased to approximately 20%.
3. The vast majority of protocols are domestic protocols (approximately 94-96%), while foreign protocols make up approximately 4-6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

6F. Comparison of Domestic and Foreign Minority Participation for FY 2002-2005

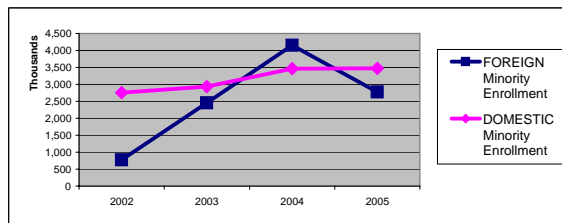
FY Reported	FY Funded	FOREIGN Minority Enrollment	Foreign Total Enrollment	DOMESTIC Minority Enrollment	Domestic Total Enrollment
2002	2001	777,461	946,083	2,754,820	10,149,869
		82.2%	100.0%	27.1%	100.0%
2003	2002	2,452,329	2,860,897	2,935,363	11,911,357
		85.7%	100.0%	24.6%	100.0%
2004	2003	4,147,255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

NOTE MINORITY % WILL NOT ADD TO 100%

Percentage Comparison of Foreign Minority Enrollment to Total Foreign Enrollment for FY 2002-2005



Number of Minority Participants for FY2002-2005



Percentage Comparison of Domestic Minority Enrollment to Total Domestic Enrollment for FY 2002-2005

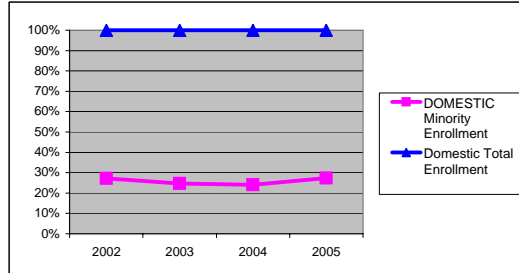


Table 6F Comments:

1. Domestic Minority Enrollment has varied from 24.1% to 27.4% of Total Domestic Enrollment.
2. Foreign Minority Enrollment has varied from 82.2% to 90.9% of Total Foreign Enrollment, reflecting that most of the foreign research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary minority data used in this report.
3. The Total Minority Enrollment reported in FY2005 was 55.5% Domestic and 44.5 % Foreign (see Table 1). The small percentage of foreign protocols account for a significant proportion (44.5%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data. A25

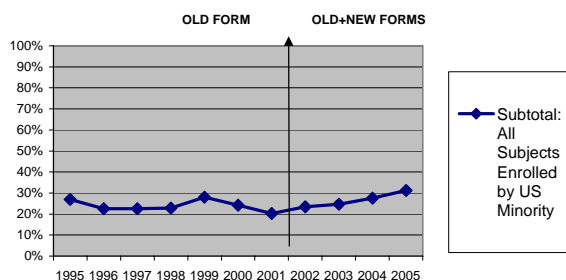
Table 7: Eleven Year Minority Trend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2005: Enrollment by Race and Ethnicity

Note: Phase III Data for years 1994-2001 is presented only by Extramural Phase III trials data

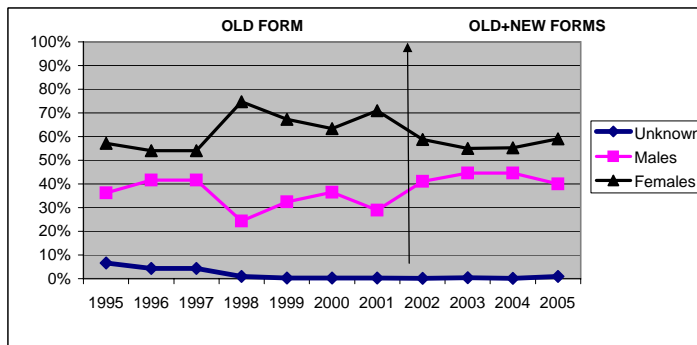
7A. Phase III ELEVEN YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER AND MINORITY CATEGORIES IN ALL PROTOCOLS (Old + New Forms)

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%	

Total Phase III Enrollment by Year Reported



Sex/Gender Phase III Enrollment by Year Reported



Note: The arrow in the graphs indicates that the old Form was used until 2001 reports, and both the OLD and NEW FORMS were used for 2002-2005 reports.

Table 7A Comments:

1. Table 7A summarizes enrollment by sex/gender and minority race/ethnicity categories for the eleven year reporting period (1995-2005). The data are compiled from Tables 7B, 7C and 7D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 7B) and the NEW Enrollment Form (Tables 7C and 7D).
2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

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

NOTE 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 (below the dark row) are from the new Population Tracking System that was deployed with data reported in FY 2002, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

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

7B. Phase III OLD FORM:Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format													
FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/Other		Total	Subtotal Using US Minority Categories (shaded): OLD FORM		Number Protocols with Enrollment data (Old Form):	
1995	1994	5,358	2,740	52,433	20,031	172,773	45,988		299,323	80,562		560	
	%	1.8%	0.9%	17.5%	6.7%	57.7%	15.4%		100.0%	26.9%			
1996	1995	4,235	40,126	46,838	19,470	321,445	57,549		489,663	110,669		608	
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%		100.0%	22.6%			
1997	1996	4,235	40,126	46,838	19,470	321,445	57,549		489,663	110,669		608	
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%		100.0%	22.6%			
1998	1997	5,030	5,324	42,805	16,440	229,534	6,378		305,511	69,599		320	
	%	1.6%	1.7%	14.0%	5.4%	75.1%	2.1%		100.0%	22.8%			
1999	1998	3,685	20,276	76,921	40,567	336,703	26,777		504,929	141,449		578	
	%	0.7%	4.0%	15.2%	8.0%	66.7%	5.3%		100.0%	28.0%			
2000	1999	3,726	24,017	62,512	30,084	335,824	39,580		495,743	120,339		589	
	%	0.8%	4.8%	12.6%	6.1%	67.7%	8.0%		100.0%	24.3%			
2001	2000	4,079	11,132	70,110	32,552	422,802	41,062		581,737	117,873		645	
	%	0.7%	1.9%	12.1%	5.6%	72.7%	7.1%		100.0%	20.3%			
2002	2001	1,645	20,560	51,991	29,636	315,543	12,228		431,603	103,832		660	
	%	0.4%	4.8%	12.0%	6.9%	73.1%	2.8%		100.0%	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%			

ORIENTATION TO TABLES 7C and 7D.

1. The New Form consists of Parts A and B (Tables 7C and 7D) for reporting years 2002-2005. This Form is provided as part of the annual progress report.
2. Table 7C displays the New Form Part A for reporting separate race and ethnicity data
3. Table 7D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the "Hispanic or Latino" column in Part A.

7C. Phase III New Form 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	159	799	4,647	52	34,654	560	2,273	43,144	36,224	1,629	5,291	43,144
	%	0.4%	1.9%	10.8%	0.1%	80.3%	1.3%	5.3%	100.0%	84.0%	3.8%	12.3%	100.0%
2003	2002	484	2,609	21,641	220	47,869	989	8,138	81,950	64,295	7,831	9,824	81,950
	%	0.6%	3.2%	26.4%	0.3%	58.4%	1.2%	9.9%	100.0%	78.5%	9.6%	12.0%	100.0%
2004	2003	1,396	4,385	43,721	611	106,793	4,419	5,657	166,982	145,742	13,435	7,805	166,982
	%	0.8%	2.6%	26.2%	0.4%	64.0%	2.6%	3.4%	100.0%	87.3%	8.0%	4.7%	100.0%
2005	2004	2,164	9,192	50,338	462	101,238	3,063	10,254	176,711	156,650	10,397	9,664	176,711
	%	1.2%	5.2%	28.5%	0.3%	57.3%	1.7%	5.8%	100.0%	88.6%	5.9%	5.5%	100.0%

7D. Phase III New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)												
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total Hispanic or Latino**	Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B		Number of Protocols with Enrollment data (New Form):
2002	2001	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%			
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%			
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%			
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%			

* These totals must agree

** These totals must agree

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

7E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2005

		ENROLLMENT					PROTOCOLS				
FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC Enrollment	Percent DOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGN Enrollment	Number of Protocols with Enrollment data (Old + New Forms):	Number of DOMESTIC Protocols	Percent Domestic Protocols	Number of FOREIGN Protocols	Percent Foreign Protocols
2002	2001	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%

Percentage of Phase III Domestic and Foreign Enrollment

Number of Phase III Domestic and Foreign protocols

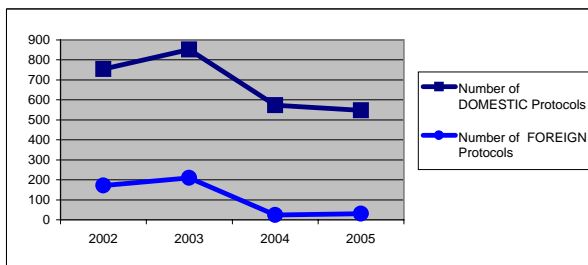
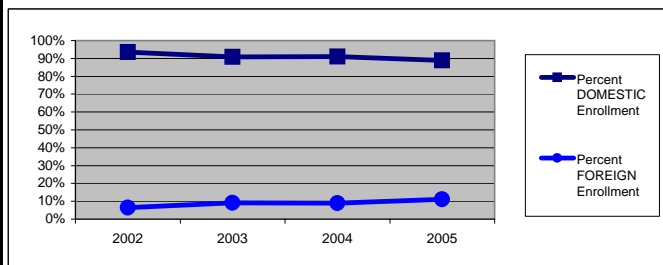


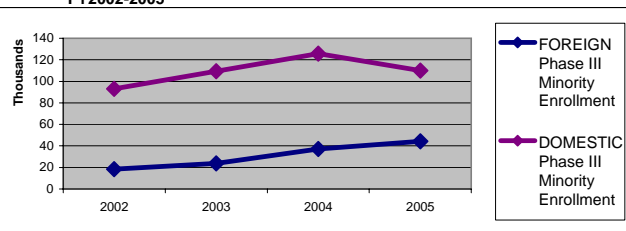
Table 7 E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2005.
2. The Domestic enrollment decreased to approximately 88.8%, while the Foreign enrollment increased to approximately 11%.
3. The vast majority of protocols are domestic protocols (approximately 94-96%), while foreign protocols make up approximately 4-6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

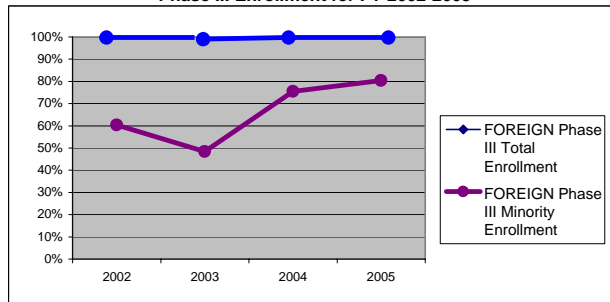
7F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2005

FY Reported	FY Funded	FOREIGN Phase III Minority Enrollment	FOREIGN Phase III Total Enrollment	DOMESTIC Phase III Minority Enrollment	DOMESTIC Phase III Total Enrollment
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%

Number of Minority Participants in Phase III Clinical Studies for FY2002-2005



Percentage Comparison of Phase III Foreign Minority Enrollment to Total Foreign Phase III Enrollment for FY 2002-2005



Percentage Comparison of Phase III Domestic Minority to Total Domestic Phase III Enrollment for FY 2002-2005

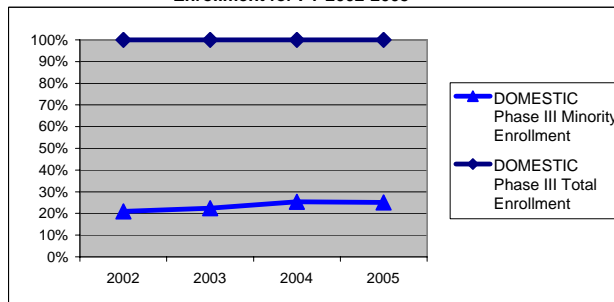


Table 7F Comments:

1. Domestic Minority Enrollment has varied from 20.9% to 25.4% of Total Domestic Enrollment.
2. Foreign Minority Enrollment has varied from 48.4% to 80.4% of Total Foreign Enrollment, reflecting that most of the foreign research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary minority data used in this report.
3. The Total Minority Enrollment reported in FY2005 was 71.3% Domestic and 28.7 % Foreign (see Table 3). The small percentage of foreign protocols (5.5%) account for a significant proportion (28.7%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

Table 8. DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2005: Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: Summary Totals for Domestic Protocols are shown in Table 8A. Table 8A includes Subtotals from OLD FORM (Table 8B) and NEW Form (Table 8C and 8D).

NOTE 2: The shaded portions of the Tables A, B, C and D show the race/ethnicity categories that are identified as minority categories.

NOTE 3: 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 allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

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

FY Reported	FY Funded	Females	Males	Unknown sex	Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	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%	

Table 8A Comments:

1. There were approximately an average of 62% females, 36% males and 2% of unknown sex enrolled in domestic protocols from 2002-2005.
2. There were approximately an average of 26% domestic minority subjects enrolled in domestic protocols from 2002-2005.
3. Total domestic enrollment ranged from 10.1M to 12.7M during these 4 years.
4. The number of domestic protocols increased from 8,425 to 9,862 in 2005.

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: 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.

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

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Domestic Protocols with Enrollment data (Old Form):
2002	2001	45,639	752,203	673,726	378,300	3,880,431	316,053	6,046,352	1,849,868	5,783
	%	0.8%	12.4%	11.1%	6.3%	64.2%	5.2%	100.0%	30.6%	
2003	2002	36,238	249,420	455,329	264,336	3,100,815	266,339	4,372,477	1,005,323	4,478
	%	0.8%	5.7%	10.4%	6.0%	70.9%	6.1%	100.0%	23.0%	
2004	2003	28,953	196,647	322,078	194,762	2,273,619	157,464	3,173,523	742,440	2,702
	%	0.9%	6.2%	10.1%	6.1%	71.6%	5.0%	100.0%	23.4%	
2005	2004	22,375	89,119	210,465	126,351	1,245,337	93,239	1,786,886	448,310	1,736
	%	1.3%	5.0%	11.8%	7.1%	69.7%	5.2%	100.0%	25.1%	

8C. NEW FORM: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)
Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	74,593	174,215	473,699	7,623	2,626,547	30,200	716,640	4,103,517	2,785,590	285,921	1,032,006	4,103,517
	%	1.8%	4.2%	11.5%	0.2%	64.0%	0.7%	17.5%	100.0%	67.9%	7.0%	25.1%	100.0%
2003	2002	61,526	295,061	897,518	23,068	5,161,965	94,138	1,005,604	7,538,880	6,003,326	602,018	933,536	7,538,880
	%	0.8%	3.9%	11.9%	0.3%	68.5%	1.2%	13.3%	100.0%	79.6%	8.0%	12.4%	100.0%
2004	2003	97,854	485,137	1,280,129	42,945	7,772,927	172,185	1,335,093	11,186,270	8,893,158	720,551	1,572,561	11,186,270
	%	0.9%	4.3%	11.4%	0.4%	69.5%	1.5%	11.9%	100.0%	79.5%	6.4%	14.1%	100.0%
2005	2004	291,044	655,959	1,232,957	42,993	7,485,193	164,096	1,010,730	10,882,972	9,120,293	721,138	1,041,541	10,882,972
	%	2.7%	6.0%	11.3%	0.4%	68.8%	1.5%	9.3%	100.0%	83.8%	6.6%	9.6%	100.0%

8D: NEW FORM
Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	Domestic Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Domestic Protocols with Enrollment data (New Form):
2002	2001	1,163	436	12,005	98	69,313	5,626	75,309	163,950	904,952	2,642
	%	0.7%	0.3%	7.3%	0.1%	42.3%	3.4%	45.9%	100.0%	22.1%	
2003	2002	3,756	1,950	13,345	678	349,844	23,560	208,885	602,018	1,930,040	5,100
	%	0.6%	0.3%	2.2%	0.1%	58.1%	3.9%	34.7%	100.0%	25.6%	
2004	2003	6,293	5,026	12,498	2,037	356,575	51,031	287,091	720,551	2,721,916	7,058
	%	0.9%	0.7%	1.7%	0.3%	49.5%	7.1%	39.8%	100.0%	24.3%	
2005	2004	22,057	7,810	19,282	1,981	362,707	36,503	270,798	721,138	3,020,554	8,126
	%	3.1%	1.1%	2.7%	0.3%	50.3%	5.1%	37.6%	100.0%	27.8%	

* These totals must agree

** These totals must agree

Table 9. DOMESTIC PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2005:Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: Summary Totals for Domestic Protocols are shown in Table 9A. Table 9A includes Subtotals from OLD FORM (Table 9B) and NEW Form (Table 9Cand 9D).

NOTE 2: The shaded portions of the Tables A, B, C and D show the race/ethnicity categories that are identified as minority categories.

NOTE 3: 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 allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

9A . SUMMARY TOTALS: DOMESTIC SUBJECTS IN Phase III 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%	

Table 9A Comments:

1. There were approximately an average of 57% females, 42% males and 0.3% of unknown sex enrolled in domestic protocols from 2002-2005.
2. There were approximately an average of 23.5% domestic minority subjects enrolled in domestic Phase III protocols from 2002-2005.
3. Total domestic Phase III enrollment ranged from 437,902 to 496,241 during these 4 years.
4. The number of domestic Phase III protocols ranged from 643 to 517 in 2005.

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.

9B. OLD FORM: Total of All Phase III 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%	

9C. NEW FORM: Inclusion Enrollment Report (Total of All Phase III Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

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

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	159	798	3,199	52	34,541	560	1,520	40,829	34,662	1,629	4,538	40,829
	%	0.4%	2.0%	7.8%	0.1%	84.6%	1.4%	3.7%	100.0%	84.9%	4.0%	11.1%	100.0%
2003	2002	477	2,586	14,031	220	46,774	989	6,878	71,955	55,575	7,828	8,552	71,955
	%	0.7%	3.6%	19.5%	0.3%	65.0%	1.4%	9.6%	100.0%	77.2%	10.9%	11.9%	100.0%
2004	2003	1,396	4,373	22,307	611	106,260	1,849	4,884	141,680	123,770	10,863	7,047	141,680
	%	1.0%	3.1%	15.7%	0.4%	75.0%	1.3%	3.4%	100.0%	87.4%	7.7%	5.0%	100.0%
2005	2004	1,775	4,920	24,390	462	93,662	3,063	9,048	137,320	118,528	9,773	9,019	137,320
	%	1.3%	3.6%	17.8%	0.3%	68.2%	2.2%	6.6%	100.0%	86.3%	7.1%	6.6%	100.0%

9D. NEW FORM

Part B: Hispanic Enrollment Report: Number of Phase III 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%	

* These totals must agree

** These totals must agree

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

Table 10. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Clinical Research Reported in FY2002-2005: Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: Summary Totals for Domestic Protocols are shown in Table 10A. Table 10A includes Subtotals from OLD FORM (Table 10B) and NEW Form (Table 10C and 10D).

NOTE 2: The shaded portions of the Tables A, B, C and D show the race/ethnicity categories that are identified as minority categories.

NOTE 3: 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 allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

10A. 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%	

Table 10AComments:

1. The percent females varied from 39.2% to 58.5% in foreign protocols from 2002-2005; the percent males varied from 40.1% to 60.4%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in foreign protocols increased from 82.2% to 90.9% from 2002 to 2005.
3. Total foreign enrollment ranged from 777,461 to 4.15M during these 4 years.
4. The number of foreign protocols ranged from 638 in 2003 to 371 in 2005.

NOTE on FY2002 Reported Data:

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

NOTE on FY2003 Reported Data:

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

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

NOTE on FY2004 Reported Data:

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

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

NOTE on FY2005 Reported Data:

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

NOTE: 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.

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

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

10C. NEW FORM: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)
Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race							Total of All Subjects by Ethnicity				
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	3,271	180,022	68,071	14,013	19,970	741	3,153	289,241	278,618	6,064	4,559	289,241
	%	1.1%	62.2%	23.5%	4.8%	6.9%	0.3%	1.1%	100.0%	96.3%	2.1%	1.6%	100.0%
2003	2002	2,018	1,842,941	62,572	14,501	253,745	5,324	7,018	2,188,119	2,158,933	9,623	19,563	2,188,119
	%	0.1%	84.2%	2.9%	0.7%	11.6%	0.2%	0.3%	100.0%	98.7%	0.4%	0.9%	100.0%
2004	2003	193	3,860,259	99,728	11,507	292,142	14,056	46,157	4,324,042	4,275,684	35,788	12,570	4,324,042
	%	0.0%	89.3%	2.3%	0.3%	6.8%	0.3%	1.1%	100.0%	98.9%	0.8%	0.3%	100.0%
2005	2004	1,171	2,390,404	125,305	10,293	187,697	18,857	94,999	2,828,726	2,683,871	52,801	92,054	2,828,726
	%	0.0%	84.5%	4.4%	0.4%	6.6%	0.7%	3.4%	100.0%	94.9%	1.9%	3.3%	100.0%

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

FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Foreign Protocols with Enrollment data (New Form):
2002	2001	1,461	0	4	0	1,659	683	175	3,982	267,952	102
	%	36.7%	0.0%	0.1%	0.0%	41.7%	17.2%	4.4%	100.0%	92.6%	
2003	2002	1,644	3	1,222	0	632	4,528	1,594	9,623	1,929,582	213
	%	17.1%	0.0%	12.7%	0.0%	6.6%	47.1%	16.6%	100.0%	88.2%	
2004	2003	115	14	12,778	0	4,537	11,878	6,466	35,788	3,996,746	285
	%	0.3%	0.0%	35.7%	0.0%	12.7%	33.2%	18.1%	100.0%	92.4%	
2005	2004	682	6	164	0	26,161	14,664	11,124	52,801	2,583,315	321
	%	1.3%	0.0%	0.3%	0.0%	49.5%	27.8%	21.1%	100.0%	91.3%	

* These totals must agree

** These totals must agree

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

Table 11. FOREIGN PROTOCOLS: Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY2002-2005: Enrollment Using U.S. Race/Ethnicity Categories

NOTE 1: Summary Totals for Domestic Protocols are shown in Table 11A. Table 11A includes Subtotals from OLD FORM (Table 11B) and NEW Form (Table 11C and 11D).

NOTE 2: The shaded portions of the Tables A, B, C and D show the race/ethnicity categories that are identified as minority categories.

NOTE 3: 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 allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

11A. SUMMARY TOTALS: FOREIGN SUBJECTS IN in Phase III Clinical Research FOREIGN PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):
2002	2001	14,359	15,911	41	30,311	18,308	172
	%	47.4%	52.5%	0.1%	100.0%	60.4%	
2003	2002	28,037	21,237	136	49,410	23,927	209
	%	56.7%	43.0%	0.3%	100.0%	48.4%	
2004	2003	24,020	25,023	83	49,126	37,126	24
	%	48.9%	50.9%	0.2%	100.0%	75.6%	
2005	2004	29,388	23,163	2,547	55,098	44,281	30
	%	53.3%	42.0%	4.6%	100.0%	80.4%	

Table 11A Comments:

1. The percent females varied from 47.4% to 56.7% in Phase III foreign protocols from 2002-2005; the percent males varied from 42.0% to 52.5%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in Phase III foreign protocols increased from 60.4% to 80.4% from 2002 to 2005.
3. Total Phase III foreign enrollment increased from 30,311 to 55,098 during these 4 years.
4. The number of Phase III foreign protocols dropped from 209 in 2003 to 30 in 2005.

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.

11B. OLD FORM: Total of All FOREIGN Subjects in Phase III Clinical Research 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%	

11C. NEW FORM: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported in Phase III Clinical Research Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

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

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown /Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	0	1	1,448	0	113	0	753	2,315	1,562	0	753	2,315
	%	0.0%	0.0%	62.5%	0.0%	4.9%	0.0%	32.5%	100.0%	67.5%	0.0%	32.5%	100.0%
2003	2002	7	23	7,610	0	1,095	0	1,260	9,995	8,720	3	1,272	9,995
	%	0.1%	0.2%	76.1%	0.0%	11.0%	0.0%	12.6%	100.0%	87.2%	0.0%	12.7%	100.0%
2004	2003	0	12	21,414	0	553	2,570	753	25,302	21,972	2,572	758	25,302
	%	0.0%	0.0%	84.6%	0.0%	2.2%	10.2%	3.0%	100.0%	86.8%	10.2%	3.0%	100.0%
2005	2004	389	4,272	25,948	0	7,576	0	1,206	39,391	38,122	624	645	39,391
	%	1.0%	10.8%	65.9%	0.0%	19.2%	0.0%	3.1%	100.0%	96.8%	1.6%	1.6%	100.0%

11D. NEW FORM

Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled in Phase III Clinical Research 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%	

* These totals must agree

** These totals must agree

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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 Tracking User Group. The availability of training documents on the eRA Population Tracking User Group website has been widely distributed to NIH extramural staff. A training subcommittee of the full NIH Tracking and Inclusion committee has been established to develop new training documents and methods of training for NIH staff and the extramural research community during FY2007.

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

Communication and Outreach Efforts to the Scientific Community

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

- ▶ The slide show, “Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know!” was made available to Institute and Center staff to assist them in working with the extramural community. This information was also presented at regional meetings attended by extramural scientists and administrators, faculty and students.
- ▶ The *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research* was published in the fall of 2002 and is available to the research community and NIH staff. This publication discusses the elements of recruitment and retention, the NIH inclusion policy, 1997 OMB requirements for reporting race and ethnicity data, as well as information for application submission, peer review, and funding. The publication is posted on the ORWH website <http://orwh.od.nih.gov> as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm.
- ▶ In addition, the *Frequently Asked Questions (FAQs) for the Inclusion, Recruitment and Retention of Women and Minority Subjects in Clinical Research* complements the *Outreach Notebook* and provides additional guidance to researchers and NIH staff in a user friendly format. The *FAQs* is posted on the ORWH website <http://orwh.od.nih.gov> as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm.

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

Monitoring Compliance: Extramural and Intramural Population Data Analysis

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

NIH has monitored aggregate demographic data for study populations through the evolving NIH computerized tracking system since fiscal year 1994, and tracking the inclusion of women and minorities in clinical studies is well established in all ICs. Members of the NIH Tracking and Inclusion Committee continue to work on ways to refine and improve data collection methods and the quality of the data entered by each IC into this system. In May 2002, the NIH deployed a new population tracking system for monitoring the inclusion of women and minorities in clinical research. This system provides easier

data entry and project monitoring for NIH staff, creates clear and timely NIH reports on inclusion data, and incorporates the 1997 OMB Office of Management and Budget (OMB) standards for the classification of federal data on race and ethnicity. Following the implementation of the population tracking module, an *eRA Population Tracking User Group* consisting of representatives from several ICs, was formed to evaluate the system, recommend improvements and modifications, and provide continuous feedback related to system use. The re-engineered population tracking system continues to be refined based on input from the NIH user community.

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

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

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

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

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

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

Conclusion and Current Status

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

References

1. Public Law 103-43. National Institutes of Health Revitalization Act of 1993. 42 USC 289 (a)(1).
2. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508-14513 (1994).
3. *Women's Health: NIH Has Increased Its Efforts to Include Women in Research* (GAO/HEHS-00-96, May, 2000).
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5. Hayunga, E.G., Costello, M.D. Pinn, V.W., Demographics of Study Populations, *Applied Clinical Trials*, Vol. 6, No.1, p. 41-45, 1997.
6. Hayunga, E.G. and Pinn V.W., Implementing the 1994 NIH Guidelines, *Applied Clinical Trials*, Vol. 5, No.10, p. 34-40, 1996.
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9. McCarthy, C.R., Historical Background of Clinical Trials Involving Women and Minorities, *Academic Medicine*, Vol. 69, No.9, p. 695-698, 1994.
10. Pinn, V.W., The Role of the NIH's Office of Research on Women's Health, *Academic Medicine*, Vol. 69, No. 9, p. 698-702, 1994.
11. Gallin, J, (2002). Principles and Practices of Clinical Research: Chapter 11 NIH Policy on the Inclusion of Women and Minorities as Subjects of Clinical Research, Academic Press, San Diego, California, pp 146-157.

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

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

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

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

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

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

Appendix B

Explanation of Sex and Minority Codes

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

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

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

Appendix C

NIH Tracking and Inclusion Committee Members

- Full Committee

<p style="text-align: center;">NIH Tracking and Inclusion Committee 2006 List of Members</p>
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Office of the Director

Office of Research on Women's Health

Vivian Pinn (Co-Chair), Angela Bates, Lisa Begg, Joyce Rudick

Office of Extramural Research

Carlos Caban*, Viktoriya Anufriyeva, Maria Koshy

Office of Acquisition, Management and Procurement

Barbara Levy

National Cancer Institute

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

National Eye Institute

Lore Anne McNicol*, William Darby, Pavi Miskala

National Heart, Lung, and Blood Institute

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

National Human Genome Research Institute

Bettie Graham*, Pam Sellman

National Institute on Aging

Robin Barr *, Karen Bashir, Kate Nagy

National Institute on Alcohol Abuse and Alcoholism

Dorita Sewell*, Van Van

National Institute of Allergy and Infectious Diseases

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

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Madeline Turkeltaub*

National Institute of Child Health and Human Development

Eugene Hayunga*, Sandi Delcore

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

List of Members, continued...

National Institute on Deafness and Other Communication Disorders

Castilla McNamara*, Lana Shekim

National Institute of Dental and Craniofacial Research

Maria Canto*, Trenita Davis

National Institute of Diabetes, Digestive and Kidney Disorders

Patricia Robuck*, Christine Densmore, Lauren Meskill, Donna James, Garman Williams

National Institute on Drug Addiction

Christie Baxter*

National Institute of Environmental Health Sciences

Martha Barnes *

National Institute of General Medical Sciences

Lori Burge *, Alison Cole

National Institute of Mental Health

Catherine Roca *, Sue Kennel, Ernesto Marquez, Dawn Corbett, Kathleen O’Leary

National Institute of Neurological Disorders and Stroke

Frances Yee *, Kristy Woolbert

National Institute of Nursing Research

Paul Cotton *, Christine Shaw

National Library of Medicine

Hua-Chuan Sim *

Warren G. Magnuson Clinical Center

Kim Jarema *, Dee Koziol

National Center for Complementary and Alternative Medicine

April Bower *

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

List of Members, continued...

National Center for Research Resources

Sheila McClure*, Delores Lee, Patricia Newman, Stephen Seidel, Louise Ramm

Fogarty International Center

Aron Primack*

Center for Scientific Review

Anita Miller Sostek*

National Center for Minority Health and Health Disparities

Derrick Tabor*, Ivy Chan

National Institute of Biomedical Imaging and Bioengineering

Andrea Brooks*, 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; (b) the manner in which clinical trials are required to be designed and carried out; and (c) the operation of outreach programs 492B(d)(1)

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

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

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

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

The statute speaks specifically to outreach and states that:

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

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

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

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

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

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

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

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

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

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

II. POLICY

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

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

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

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

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

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

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

1. Prior Studies Support the Existence of Significant Differences

If the data from prior studies strongly support the existence of significant differences of clinical or public health importance in intervention effect based on sex/gender, racial/ethnic, and relevant subpopulation comparisons, the primary question(s) to be addressed by the proposed NIH-

defined Phase III clinical trial and the design of that trial must specifically accommodate this. For example, if men and women are thought to respond differently to an intervention, then the Phase III clinical trial must be designed to answer two separate primary questions, one for men and the other for women, with adequate sample size for each.

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

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

2. Prior Studies Support No Significant Differences

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

3. Prior Studies Neither Support nor Negate Significant Differences

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

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

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

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

III. ROLES AND RESPONSIBILITIES

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

1. NIH Staff

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

2. Principal Investigators

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

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

Investigators and their staff(s) are urged to develop appropriate and culturally sensitive outreach programs and activities commensurate with the goals of the study or objectives of the contract. The objective should be to actively recruit and retain the most diverse study population consistent with the purposes of the research project. Indeed, the purpose should be to establish a

relationship between the investigator(s) and staff(s) and populations and community(ies) of interest such that mutual benefit is derived for participants in the study. Investigator(s) should take precautionary measures to ensure that ethical issues are considered, such that there is minimal possibility of coercion or undue influence in the incentives or rewards offered in recruiting into or retaining participants in studies.

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

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

3. Institutional Review Boards (IRBs)

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

4. Peer Review Groups

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

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

The review instructions for grants are available on line at the following URL:

http://grants.nih.gov/grants/peer/hs_review_inst.pdf

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

Or contact:

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

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Appendix F

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

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

Release Date: August 8, 2001

NOTICE: NOT-OD-01-053

National Institutes of Health

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

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

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

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

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

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

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

Ethnic Categories:

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

Not Hispanic or Latino

Racial Categories:

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

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

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

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

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

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

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

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

NIH requires all grants, contracts, and intramural projects conducting clinical research to address the Inclusion of Women and Minorities (see

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

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

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

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

<http://grants.nih.gov/grants/funding/phs398/enrollment.pdf>

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

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

http://grants.nih.gov/grants/funding/women_min/InclusionOld_Form.pdf

Annual Progress Reports (type 5) and Competing Supplement Applications

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

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

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

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

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

III. Frequently Asked Questions

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

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

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

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

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

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

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

Neither the Targeted/Planned Enrollment 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:

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APPENDIX G

NIH Inclusion Tables for Target and Enrollment Data

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

Old Table for Target & Enrollment Data Collection

INCLUSION TABLE

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

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

Grant Number (if known): _____

STUDY TITLE: _____

Total Enrollment: _____ Protocol Number: _____

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

New Table for Target Data Collection

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

Targeted/Planned Enrollment Table

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

Study Title:

Total Planned Enrollment:

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

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

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 FY2004 and Reported in FY2005*

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Table 1A. Aggregate Enrollment Data for All Extramural and Intramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	9,503,922	3,714,289		39.08%
%	60.45%	59.47%		
Males	5,941,907	2,493,792		41.97%
%	37.79%	39.93%		
Unknown	276,923	37,356		13.49%
%	1.76%	0.60%		
TOTAL	15,722,752	6,245,437	39.72%	
Total %	100%	100.00%		100.00%

Total Number of Protocols with Enrollment Data:	10,233
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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: 8,447			
	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	269,164	1,598,780	863,143	30,490	4,837,167	109,736	683,644	8,392,124	7,214,587	511,731	665,806	8,392,124
	1.96%	11.66%	6.29%	0.22%	35.28%	0.80%	4.99%	61.20%	52.62%	3.73%	4.86%	61.20%
	3.21%	19.05%	10.29%	0.36%	57.64%	1.31%	8.15%	100.00%	85.97%	6.10%	7.93%	100.00%
	92.11%	52.48%	63.55%	57.22%	63.04%	59.98%	61.83%	61.20%	61.12%	66.12%	58.73%	61.20%
Male	22,333	1,441,120	474,386	21,827	2,691,434	72,109	338,312	5,061,521	4,421,319	255,280	384,922	5,061,521
	0.16%	10.51%	3.46%	0.16%	19.63%	0.53%	2.47%	36.91%	32.24%	1.86%	2.81%	36.91%
	0.44%	28.47%	9.37%	0.43%	53.17%	1.42%	6.68%	100.00%	87.35%	5.04%	7.60%	100.00%
	7.64%	47.31%	34.93%	40.96%	35.08%	39.41%	30.60%	36.91%	37.46%	32.98%	33.96%	36.91%
Unknown	718	6,470	20,733	969	144,289	1,108	83,766	258,053	168,258	6,928	82,867	258,053
	0.01%	0.05%	0.15%	0.01%	1.05%	0.01%	0.61%	1.88%	1.23%	0.05%	0.60%	1.88%
	0.28%	2.51%	8.03%	0.38%	55.91%	0.43%	32.46%	100.00%	65.20%	2.68%	32.11%	100.00%
	0.25%	0.21%	1.53%	1.82%	1.88%	0.61%	7.58%	1.88%	1.43%	0.90%	7.31%	1.88%
Total	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
	2.13%	22.22%	9.91%	0.39%	55.96%	1.33%	8.06%	100.00%	86.09%	5.64%	8.27%	100.00%
	2.13%	22.22%	9.91%	0.39%	55.96%	1.33%	8.06%	100.00%	86.09%	5.64%	8.27%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								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	18,244	5,693	12,224	1,273	268,670	29,134	176,493	511,731	3,316,476
	2.36%	0.74%	1.58%	2.49%	34.71%	3.76%	22.80%	66.12%	24.19%
	3.57%	1.11%	2.39%	4.37%	52.50%	5.69%	34.49%	100.00%	39.52%
	80.23%	72.84%	62.86%	64.26%	69.09%	56.94%	62.60%	66.12%	59.18%
Male	4,354	2,062	7,061	659	117,005	21,276	102,863	255,280	2,251,643
	0.56%	0.27%	0.91%	1.29%	15.12%	2.75%	13.29%	32.98%	16.42%
	1.71%	0.81%	2.77%	3.10%	45.83%	8.33%	40.29%	100.00%	44.49%
	19.15%	26.38%	36.31%	33.27%	30.09%	41.58%	36.49%	32.98%	40.18%
Unknown	141	61	161	49	3,199	756	2,561	6,928	35,758
	0.02%	0.01%	0.02%	0.10%	0.41%	0.10%	0.33%	0.90%	0.26%
	2.04%	0.88%	2.32%	6.48%	46.17%	10.91%	36.97%	100.00%	13.86%
	0.62%	0.78%	0.83%	2.47%	0.82%	1.48%	0.91%	0.90%	0.64%
TOTAL	22,739	7,816	19,446	1,981	388,874	51,166	281,917	773,939	5,603,877
	2.94%	1.01%	2.51%	3.87%	50.25%	6.61%	36.43%	100.00%	40.87%
	2.94%	1.01%	2.51%	3.87%	50.25%	6.61%	36.43%	100.00%	40.87%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	11,837	170,391	132,806	82,779	677,824	36,161	1,111,798	397,813
	0.59%	8.47%	6.60%	4.12%	33.70%	1.80%	55.28%	19.78%
	<i>1.06%</i>	<i>15.33%</i>	<i>11.95%</i>	<i>7.45%</i>	<i>60.97%</i>	<i>3.25%</i>	<i>100.00%</i>	<i>35.78%</i>
	52.90%	66.93%	57.84%	61.33%	53.49%	35.31%	55.28%	62.01%
Male	10,422	83,995	96,547	51,185	584,294	53,943	880,386	242,149
	0.52%	4.18%	4.80%	2.55%	29.05%	2.68%	43.78%	12.04%
	<i>1.18%</i>	<i>9.54%</i>	<i>10.97%</i>	<i>5.81%</i>	<i>66.37%</i>	<i>6.13%</i>	<i>100.00%</i>	<i>27.50%</i>
	46.58%	32.99%	42.05%	37.92%	46.11%	52.68%	43.78%	37.74%
Unknown	116	212	262	1,008	4,971	12,301	18,870	1,598
	0.006%	0.01%	0.01%	0.05%	0.25%	0.61%	0.94%	0.08%
	<i>0.61%</i>	<i>1.12%</i>	<i>1.39%</i>	<i>5.34%</i>	<i>26.34%</i>	<i>65.19%</i>	<i>100.00%</i>	<i>8.47%</i>
	0.52%	0.08%	0.11%	0.75%	0.39%	12.01%	0.94%	0.25%
Total	22,375	254,598	229,615	134,972	1,267,089	102,405	2,011,054	641,560
	1.11%	12.66%	11.42%	6.71%	63.01%	5.09%	100.00%	31.90%
	<i>1.11%</i>	<i>12.66%</i>	<i>11.42%</i>	<i>6.71%</i>	<i>63.01%</i>	<i>5.09%</i>	<i>100.00%</i>	<i>31.90%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

1,786

Legend

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

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

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

Data Table Comments:

Sex/Gender:

More females (9,503,922 or 60.5%) than males (5,941,907 or 37.8%) are enrolled in aggregate extramural and intramural research protocols.
More minority females (3,714,289 or 59.5%) than minority males (2,493,792 or 39.9%) are enrolled in aggregate extramural and intramural research protocols.

Minority:

Approximately 39.7% (6,245,437) of participants in aggregate extramural and intramural research (15,722,752) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 63% following the 1977 OMB standards and 56% following the 1997 OMB standards.
Largest identified racial minority group is Asian/Pacific Islander at 12.6% following the 1977 OMB standards.
Largest identified racial minority group is Asians at 22.2% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 1.1%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.4%.

Ethnicity:

5.64% 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 is White at 50.3%

Smallest identified racial group is Asian at 1%

Of the 773,939 participants, 66.1% are women and 33% are men.

6.7% of participants identified as Hispanic according to the 1977 OMB standards.

Table 2A. Aggregate Enrollment Data for Extramural and Intramural Phase III Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	290,977	85,015		29.22%
%	59.02%	55.14%		
Males	197,300	66,589		33.75%
%	40.02%	43.19%		
Unknown	4,723	2,587		54.77%
%	0.96%	1.68%		
TOTAL	493,000	154,191	31.28%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 547

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 337			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	1,531	5,122	24,512	206	47,828	1,637	4,467	85,303	75,266	6,164	3,872	85,302
	0.87%	2.90%	13.87%	0.12%	27.07%	0.93%	2.53%	48.27%	42.59%	3.49%	2.19%	48.27%
	1.79%	6.00%	28.74%	0.24%	56.07%	1.92%	5.24%	100.00%	88.23%	7.23%	4.54%	100.00%
	70.75%	55.72%	48.69%	44.59%	47.24%	53.44%	43.56%	48.27%	48.05%	59.29%	40.07%	48.27%
Male	629	4,032	23,303	256	53,144	1,422	4,005	86,791	78,594	4,214	3,983	86,791
	0.36%	2.28%	13.19%	0.14%	30.07%	0.80%	2.27%	49.11%	44.48%	2.38%	2.25%	49.11%
	0.72%	4.65%	26.85%	0.29%	61.23%	1.64%	4.61%	100.00%	90.56%	4.86%	4.59%	100.00%
	29.07%	43.86%	46.29%	55.41%	52.49%	46.43%	39.06%	49.11%	50.17%	40.53%	41.21%	49.11%
Unknown	4	38	2,523	0	266	4	1,782	4,617	2,790	18	1,809	4,617
	0.00%	0.02%	1.43%	0.00%	0.15%	0.00%	1.01%	2.61%	1.58%	0.01%	1.02%	2.61%
	0.09%	0.82%	54.65%	0.00%	5.76%	0.09%	38.60%	100.00%	60.43%	0.39%	39.18%	100.00%
	0.18%	0.41%	5.01%	0.00%	0.26%	0.13%	17.38%	2.61%	1.78%	0.17%	18.72%	2.61%
Total	2,164	9,192	50,338	462	101,238	3,063	10,254	176,711	156,650	10,396	9,664	176,710
	1.22%	5.20%	28.49%	0.26%	57.29%	1.73%	5.80%	100.00%	88.65%	5.88%	5.47%	100.00%
	1.22%	5.20%	28.49%	0.26%	57.29%	1.73%	5.80%	100.00%	88.65%	5.88%	5.47%	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	709	30	234	31	1,859	223	3,079	6,165	37,946
	6.82%	0.29%	2.25%	7.33%	17.88%	2.14%	29.61%	59.30%	21.47%
	11.50%	0.49%	3.80%	13.90%	30.15%	3.62%	49.94%	100.00%	44.48%
	93.41%	71.43%	52.47%	68.89%	50.70%	52.72%	61.40%	59.30%	51.35%
Male	49	12	212	14	1,804	199	1,924	4,214	33,370
	0.47%	0.12%	2.04%	3.31%	17.35%	1.91%	18.51%	40.53%	18.88%
	1.16%	0.28%	5.03%	7.04%	42.81%	4.72%	45.66%	100.00%	38.45%
	6.46%	28.57%	47.53%	31.11%	49.20%	47.04%	38.36%	40.53%	45.16%
Unknown	1	0	0	0	4	1	12	18	2,585
	0.01%	0.00%	0.00%	0.00%	0.04%	0.01%	0.12%	0.17%	1.46%
	5.56%	0.00%	0.00%	0.00%	22.22%	5.56%	66.67%	100.00%	55.99%
	0.13%	0.00%	0.00%	0.00%	0.11%	0.24%	0.24%	0.17%	3.50%
TOTAL	759	42	446	45	3,667	423	5,015	10,397	73,901
	7.30%	0.40%	4.29%	10.64%	35.27%	4.07%	48.24%	100.00%	41.82%
	7.30%	0.40%	4.29%	10.64%	35.27%	4.07%	48.24%	100.00%	41.82%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	885	9,930	23,422	12,832	155,978	2,627	205,674	47,069
	0.28%	3.14%	7.41%	4.06%	49.32%	0.83%	65.03%	14.88%
	<i>0.43%</i>	<i>4.83%</i>	<i>11.39%</i>	<i>6.24%</i>	<i>75.84%</i>	<i>1.28%</i>	<i>100.00%</i>	<i>22.89%</i>
	67.10%	55.98%	59.44%	58.78%	67.38%	58.29%	65.03%	58.62%
Male	433	7,810	15,979	8,997	75,505	1,785	110,509	33,219
	0.14%	2.47%	5.05%	2.84%	23.87%	0.56%	34.94%	10.50%
	<i>0.39%</i>	<i>7.07%</i>	<i>14.46%</i>	<i>8.14%</i>	<i>68.32%</i>	<i>1.62%</i>	<i>100.00%</i>	<i>30.06%</i>
	32.83%	44.02%	40.55%	41.22%	32.62%	39.61%	34.94%	41.37%
Unknown	1	0	1	0	9	95	106	2
	0.000%	0.00%	0.00%	0.00%	0.00%	0.03%	0.03%	0.00%
	<i>0.94%</i>	<i>0.00%</i>	<i>0.94%</i>	<i>0.00%</i>	<i>8.49%</i>	<i>89.62%</i>	<i>100.00%</i>	<i>1.89%</i>
	0.08%	0.00%	0.00%	0.00%	0.00%	2.11%	0.03%	0.00%
Total	1,319	17,740	39,402	21,829	231,492	4,507	316,289	80,290
	0.42%	5.61%	12.46%	6.90%	73.19%	1.42%	100.00%	25.39%
	<i>0.42%</i>	<i>5.61%</i>	<i>12.46%</i>	<i>6.90%</i>	<i>73.19%</i>	<i>1.42%</i>	<i>100.00%</i>	<i>25.39%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

210

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:

Substantial numbers of women and minorities are enrolled in extramural Phase III research protocols reported in FY2005.

More females (290,977 or 59%) than males (197,300 or 40%) are enrolled in aggregate extramural and intramural Phase III research protocols.

More minority females (85,015 or 55.1%) than minority males (66,589 or 43.2%) are enrolled in aggregate extramural and intramural Phase III research protocols.

Minority:

Approximately 30% (139,456) of participants in aggregate extramural Phase III research (465,956) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 73.2% following the 1977 OMB standards and 57.3% following the 1997 OMB standards.

Largest identified racial minority group is Black at 12.5% following the 1977 OMB standards and 28.5% following the 1997 OMB standards.

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

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.3%.

Ethnicity:

5.8% 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 is White at 35.3%

Smallest identified racial group is Asian at 0.4%

Of the 10,397 participants, 59.3% are women and 40.5% are men.

6.9% of participants identified as Hispanic according to the 1977 OMB standards.

Table 3A. Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	8,558,998	3,459,235		40.42%
%	62.10%	59.30%		
Males	4,961,653	2,337,451		47.11%
%	36.00%	40.07%		
Unknown	261,548	36,591		13.99%
%	1.90%	0.63%		
TOTAL	13,782,199	5,833,277	42.32%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:

8,763

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

Number of Protocols with Enrollment Data:

7,710

	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	266,313	1,581,873	836,332	29,778	4,402,423	101,234	661,349	7,879,302	6,725,464	500,537	653,301	7,879,302
	2.10%	12.46%	6.59%	0.23%	34.68%	0.80%	5.21%	62.07%	52.98%	3.94%	5.15%	62.07%
	3.38%	20.08%	10.61%	0.38%	55.87%	1.28%	8.39%	100.00%	85.36%	6.35%	8.29%	100.00%
	92.48%	52.52%	63.83%	57.99%	64.75%	58.59%	62.34%	62.07%	62.09%	66.51%	58.86%	62.07%
Male	20,940	1,423,812	453,090	20,605	2,252,000	70,444	319,035	4,559,926	3,939,661	245,060	375,205	4,559,926
	0.16%	11.22%	3.57%	0.16%	17.74%	0.55%	2.51%	35.92%	31.04%	1.93%	2.96%	35.92%
	0.46%	31.22%	9.94%	0.45%	49.39%	1.54%	7.00%	100.00%	86.40%	5.37%	8.23%	100.00%
	7.27%	47.27%	34.58%	40.13%	33.12%	40.77%	30.07%	35.92%	36.37%	32.57%	33.80%	35.92%
Unknown	718	6,470	20,728	969	144,278	1,108	80,503	254,774	166,373	6,927	81,474	254,774
	0.01%	0.05%	0.16%	0.01%	1.14%	0.01%	0.63%	2.01%	1.31%	0.05%	0.64%	2.01%
	0.28%	2.54%	8.14%	0.38%	56.63%	0.43%	31.60%	100.00%	65.30%	2.72%	31.98%	100.00%
	0.25%	0.21%	1.58%	1.89%	2.12%	0.64%	7.59%	2.01%	1.54%	0.92%	7.34%	2.01%
Total	287,971	3,012,155	1,310,150	51,352	6,798,701	172,786	1,060,887	12,694,002	10,831,498	752,524	1,109,980	12,694,002
	2.27%	23.73%	10.32%	0.40%	53.56%	1.36%	8.36%	100.00%	85.33%	5.93%	8.74%	100.00%
	2.27%	23.73%	10.32%	0.40%	53.56%	1.36%	8.36%	100.00%	85.33%	5.93%	8.74%	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	18,231	5,666	12,192	1,251	267,973	27,818	167,406	500,537
%	2.42%	0.75%	1.62%	2.57%	35.61%	3.70%	22.25%	66.51%
	3.64%	1.13%	2.44%	4.50%	53.54%	5.56%	33.45%	100.00%
	80.26%	72.77%	62.86%	63.89%	69.05%	57.24%	63.41%	66.51%
Male	4,343	2,059	7,044	658	116,900	20,029	94,027	245,060
%	0.58%	0.27%	0.94%	1.35%	15.53%	2.66%	12.49%	32.57%
	1.77%	0.84%	2.87%	3.29%	47.70%	8.17%	38.37%	100.00%
	19.12%	26.44%	36.31%	33.61%	30.12%	41.21%	35.62%	32.57%
Unknown	141	61	161	49	3,199	756	2,560	6,927
%	0.02%	0.01%	0.02%	0.10%	0.43%	0.10%	0.34%	0.92%
	2.04%	0.88%	2.32%	6.48%	46.18%	10.91%	36.96%	100.00%
	0.62%	0.78%	0.83%	2.50%	0.82%	1.56%	0.97%	0.92%
TOTAL	22,715	7,786	19,397	1,958	388,072	48,603	263,993	752,524
%	3.02%	1.03%	2.58%	4.03%	51.57%	6.46%	35.08%	100.00%
	3.02%	1.03%	2.58%	4.03%	51.57%	6.46%	35.08%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Using US Minority Categories

3,250,909
25.61%
41.26%
59.25%
2,199,818
17.33%
48.24%
40.10%
35,752
0.28%
14.03%
0.65%
5,486,479
43.22%
43.22%
100.00%

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	Using US Minority Categories (shaded): OLD FORM
Female	3,084	54,240	98,598	52,404	452,596	18,774	679,696	208,326
	0.28%	4.98%	9.06%	4.82%	41.59%	1.73%	62.46%	19.14%
	<i>0.45%</i>	<i>7.98%</i>	<i>14.51%</i>	<i>7.71%</i>	<i>66.59%</i>	<i>2.76%</i>	<i>100.00%</i>	<i>30.65%</i>
	58.84%	60.31%	61.49%	57.40%	64.24%	50.98%	62.46%	60.07%
Male	2,042	35,517	61,487	38,587	249,418	14,676	401,727	137,633
	0.19%	3.26%	5.65%	3.55%	22.92%	1.35%	36.92%	12.65%
	<i>0.51%</i>	<i>8.84%</i>	<i>15.31%</i>	<i>9.61%</i>	<i>62.09%</i>	<i>3.65%</i>	<i>100.00%</i>	<i>34.26%</i>
	38.96%	39.49%	38.35%	42.21%	35.40%	39.85%	36.92%	39.69%
Unknown	115	175	250	299	2,561	3,374	6,774	839
	0.011%	0.02%	0.02%	0.03%	0.24%	0.31%	0.62%	0.08%
	<i>1.70%</i>	<i>2.58%</i>	<i>3.69%</i>	<i>4.41%</i>	<i>37.81%</i>	<i>49.81%</i>	<i>100.00%</i>	<i>12.39%</i>
	2.19%	0.19%	0.16%	0.33%	0.36%	9.16%	0.62%	0.24%
Total	5,241	89,932	160,335	91,290	704,575	36,824	1,088,197	346,798
	0.48%	8.26%	14.73%	8.39%	64.75%	3.38%	100.00%	31.87%
	<i>0.48%</i>	<i>8.26%</i>	<i>14.73%</i>	<i>8.39%</i>	<i>64.75%</i>	<i>3.38%</i>	<i>100.00%</i>	<i>31.87%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data: 1,053

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

More females (8,558,998 or 62.1%) than males (4,961,653 or 36%) are enrolled in aggregate extramural research protocols.

More minority females (3,459,235 or 59.3%) than minority males (2,337,451 or 40%) are enrolled in aggregate extramural research protocols.

Minority:

Approximately 42.3% (5,833,277) of participants in aggregate extramural research (13,782,199) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 64.8% following the 1977 OMB standards and 53.6% following the 1997 OMB standards.

Largest identified racial minority group is Black at 14.7% following the 1977 OMB standards and 23.7% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.5%.

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.4%.

Ethnicity:

5.9% 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 is White at 51.5%

Smallest identified racial group is Asian at 1%

Of the 752,524 participants, 66.5% are women and 32.5% are men.

8.4% of participants identified as Hispanic according to the 1977 OMB standards.

Table 4A. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	5,354,950	2,451,014		45.77%
%	51.93%	51.94%		
Males	4,694,564	2,231,374		47.53%
%	45.53%	47.29%		
Unknown	261,548	36,591		13.99%
%	2.54%	0.78%		
TOTAL	10,311,062	4,718,979	45.77%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:

7,108

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									6,243			
	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	23,366	1,359,742	575,979	23,622	2,561,178	78,066	313,628	4,935,581	4,366,027	267,900	301,754	4,935,681
	0.25%	14.28%	6.05%	0.25%	26.90%	0.82%	3.29%	51.83%	45.85%	2.81%	3.17%	51.83%
	0.47%	27.55%	11.67%	0.48%	51.89%	1.58%	6.35%	100.00%	88.46%	5.43%	6.11%	100.00%
	52.26%	49.99%	55.90%	52.36%	52.49%	52.62%	47.98%	51.83%	52.53%	52.18%	43.24%	51.83%
Male	20,629	1,353,932	433,581	20,520	2,174,357	69,171	259,570	4,331,760	3,778,566	238,565	314,629	4,331,760
	0.22%	14.22%	4.55%	0.22%	22.83%	0.73%	2.73%	45.49%	39.68%	2.51%	3.30%	45.49%
	0.48%	31.26%	10.01%	0.47%	50.20%	1.60%	5.99%	100.00%	87.23%	5.51%	7.26%	100.00%
	46.14%	49.77%	42.08%	45.49%	44.56%	46.63%	39.71%	45.49%	45.46%	46.47%	45.09%	45.49%
Unknown	718	6,470	20,728	969	144,278	1,108	80,503	254,774	166,373	6,927	81,474	254,774
	0.01%	0.07%	0.22%	0.01%	1.52%	0.01%	0.85%	2.68%	1.75%	0.07%	0.86%	2.68%
	0.28%	2.54%	8.14%	0.38%	56.63%	0.43%	31.60%	100.00%	65.30%	2.72%	31.98%	100.00%
	1.61%	0.24%	2.01%	2.15%	2.96%	0.75%	12.31%	2.68%	2.00%	1.35%	11.67%	2.68%
Total	44,713	2,720,144	1,030,288	45,111	4,879,813	148,345	653,701	9,522,115	8,310,966	513,392	697,857	9,522,215
	0.47%	28.57%	10.82%	0.47%	51.25%	1.56%	6.87%	100.00%	87.28%	5.39%	7.33%	100.00%
	0.47%	28.57%	10.82%	0.47%	51.25%	1.56%	6.87%	100.00%	87.28%	5.39%	7.33%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								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	4,016	1,921	7,623	667	121,270	22,199	110,204	267,900	2,292,249
	0.78%	0.37%	1.48%	1.56%	23.62%	4.32%	21.47%	52.18%	24.07%
	1.50%	0.72%	2.85%	3.00%	45.27%	8.29%	41.14%	100.00%	46.44%
	48.02%	47.64%	52.04%	48.83%	50.95%	51.88%	53.97%	52.18%	51.73%
Male	4,206	2,050	6,863	650	113,527	19,831	91,438	238,565	2,102,798
	0.82%	0.40%	1.34%	1.52%	22.11%	3.86%	17.81%	46.47%	22.08%
	1.76%	0.86%	2.88%	3.28%	47.59%	8.31%	38.33%	100.00%	48.54%
	50.29%	50.84%	46.86%	47.58%	47.70%	46.35%	44.78%	46.47%	47.46%
Unknown	141	61	161	49	3,199	756	2,560	6,927	35,752
	0.03%	0.01%	0.03%	0.11%	0.62%	0.15%	0.50%	1.35%	0.38%
	2.04%	0.88%	2.32%	6.48%	46.18%	10.91%	36.96%	100.00%	14.03%
	1.69%	1.51%	1.10%	3.59%	1.34%	1.77%	1.25%	1.35%	0.81%
TOTAL	8,363	4,032	14,647	1,366	237,996	42,786	204,202	513,392	4,430,799
	1.63%	0.79%	2.85%	3.19%	46.36%	8.33%	39.78%	100.00%	46.53%
	1.63%	0.79%	2.85%	3.19%	46.36%	8.33%	39.78%	100.00%	46.53%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	2,052	41,279	72,665	42,769	244,940	15,664	419,369	158,765
	0.26%	5.23%	9.21%	5.42%	31.05%	1.99%	53.16%	20.12%
	0.49%	9.84%	17.33%	10.20%	58.41%	3.74%	100.00%	37.86%
	50.48%	54.02%	56.55%	54.00%	52.36%	47.46%	53.16%	55.09%
Male	1,898	34,955	55,583	36,140	220,262	13,966	362,804	128,576
	0.24%	4.43%	7.05%	4.58%	27.92%	1.77%	45.99%	16.30%
	0.52%	9.63%	15.32%	9.96%	60.71%	3.85%	100.00%	35.44%
	46.69%	45.75%	43.26%	45.63%	47.09%	42.32%	45.99%	44.62%
Unknown	115	175	250	299	2,561	3,374	6,774	839
	0.015%	0.02%	0.03%	0.04%	0.32%	0.43%	0.86%	0.11%
	1.70%	2.58%	3.69%	4.41%	37.81%	49.81%	100.00%	12.39%
	2.83%	0.23%	0.19%	0.38%	0.55%	10.22%	0.86%	0.29%
Total	4,065	76,409	128,498	79,208	467,763	33,004	788,947	288,180
	0.52%	9.68%	16.29%	10.04%	59.29%	4.18%	100.00%	36.53%
	0.52%	9.68%	16.29%	10.04%	59.29%	4.18%	100.00%	36.53%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

865

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:

Excluding sex-specific studies, the number of females (5,354,950 or 52%) exceeds the number of males (4,694,564 or 45.5%) enrolled in extramural research protocols.
Excluding sex-specific studies, the number of minority females (2,451,014 or 52%) exceeds the number of males (2,231,374 or 47.3%) enrolled in extramural research protocols.

Minority:

Approximately 45.7% (4,718,979) of participants in aggregate extramural research excluding sex-specific studies (10,311,062) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 59.3% following the 1977 OMB standards and 51.3% following the 1997 OMB standards.
Largest identified racial minority group is Black at 16.3% following the 1977 OMB standards.
Largest identified racial minority group is Asian/Pacific Islander at 28.6% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.5%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander and American Indian/Alaska Native at 0.5%.

Ethnicity:

5.4% 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 is White at 46.3%

Smallest identified racial group is Asian at 0.8%

Of the 204,202 participants, 52.2% are women and 46.5% are men.

10% of participants identified as Hispanic according to the 1977 OMB standards.

Table 5A. Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	277,315	77,657		28.00%
%	59.52%	55.69%		
Males	183,918	59,212		32.19%
%	39.47%	42.46%		
Unknown	4,723	2,587		54.77%
%	1.01%	1.86%		
TOTAL	465,956	139,456	29.93%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:

511

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									319			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	1,523	5,033	24,029	205	42,662	1,372	4,043	78,867	69,520	5,879	3,468	78,867
	0.92%	3.04%	14.54%	0.12%	25.81%	0.83%	2.45%	47.71%	42.05%	3.56%	2.10%	47.71%
	1.93%	6.38%	30.47%	0.26%	54.09%	1.74%	5.13%	100.00%	88.15%	7.45%	4.40%	100.00%
	71.04%	55.95%	48.45%	44.47%	46.29%	53.08%	43.20%	47.71%	47.41%	59.44%	39.43%	47.71%
Male	617	3,925	23,047	256	49,237	1,209	3,534	81,825	74,314	3,993	3,518	81,825
	0.37%	2.37%	13.94%	0.15%	29.78%	0.73%	2.14%	49.50%	44.95%	2.42%	2.13%	49.50%
	0.75%	4.80%	28.17%	0.31%	60.17%	1.48%	4.32%	100.00%	90.82%	4.88%	4.30%	100.00%
	28.78%	43.63%	46.47%	55.53%	53.42%	46.77%	37.76%	49.50%	50.68%	40.37%	40.00%	49.50%
Unknown	4	38	2,523	0	266	4	1,782	4,617	2,790	18	1,809	4,617
	0.00%	0.02%	1.53%	0.00%	0.16%	0.00%	1.08%	2.79%	1.69%	0.01%	1.09%	2.79%
	0.09%	0.82%	54.65%	0.00%	5.76%	0.09%	38.60%	100.00%	60.43%	0.39%	39.18%	100.00%
	0.19%	0.42%	5.09%	0.00%	0.29%	0.15%	19.04%	2.79%	1.90%	0.18%	20.57%	2.79%
Total	2,144	8,996	49,599	461	92,165	2,585	9,359	165,309	146,624	9,890	8,795	165,309
	1.30%	5.44%	30.00%	0.28%	55.75%	1.56%	5.66%	100.00%	88.70%	5.98%	5.32%	100.00%
	1.30%	5.44%	30.00%	0.28%	55.75%	1.56%	5.66%	100.00%	88.70%	5.98%	5.32%	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	709	30	234	31	1,859	223	2,793	5,879	36,814
	7.17%	0.30%	2.37%	7.33%	18.80%	2.25%	28.24%	59.44%	22.27%
	12.06%	0.51%	3.98%	13.90%	31.62%	3.79%	47.51%	100.00%	46.68%
	93.41%	71.43%	52.47%	68.89%	50.70%	52.72%	61.96%	59.44%	51.16%
Male	49	12	212	14	1,804	199	1,703	3,993	32,561
	0.50%	0.12%	2.14%	3.31%	18.24%	2.01%	17.22%	40.37%	19.70%
	1.23%	0.30%	5.31%	7.04%	45.18%	4.98%	42.65%	100.00%	39.79%
	6.46%	28.57%	47.53%	31.11%	49.20%	47.04%	37.78%	40.37%	45.25%
Unknown	1	0	0	0	4	1	12	18	2,585
	0.01%	0.00%	0.00%	0.00%	0.04%	0.01%	0.12%	0.18%	1.56%
	5.56%	0.00%	0.00%	0.00%	22.22%	5.56%	66.67%	100.00%	55.99%
	0.13%	0.00%	0.00%	0.00%	0.11%	0.24%	0.27%	0.18%	3.59%
TOTAL	759	42	446	45	3,667	423	4,508	9,890	71,960
	7.67%	0.42%	4.51%	10.64%	37.08%	4.28%	45.58%	100.00%	43.53%
	7.67%	0.42%	4.51%	10.64%	37.08%	4.28%	45.58%	100.00%	43.53%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	759	3,937	23,347	12,800	154,983	2,622	198,448	40,843
	0.25%	1.31%	7.77%	4.26%	51.55%	0.87%	66.01%	13.59%
	<i>0.38%</i>	<i>1.98%</i>	<i>11.76%</i>	<i>6.45%</i>	<i>78.10%</i>	<i>1.32%</i>	<i>100.00%</i>	<i>20.58%</i>
	66.40%	72.54%	59.59%	58.86%	67.78%	58.37%	66.01%	60.51%
Male	383	1,490	15,831	8,947	73,667	1,775	102,093	26,651
	0.13%	0.50%	5.27%	2.98%	24.50%	0.59%	33.96%	8.86%
	<i>0.38%</i>	<i>1.46%</i>	<i>15.51%</i>	<i>8.76%</i>	<i>72.16%</i>	<i>1.74%</i>	<i>100.00%</i>	<i>26.10%</i>
	33.51%	27.46%	40.41%	41.14%	32.22%	39.51%	33.96%	39.49%
Unknown	1	0	1	0	9	95	106	2
	0.000%	0.00%	0.00%	0.00%	0.00%	0.03%	0.04%	0.00%
	<i>0.94%</i>	<i>0.00%</i>	<i>0.94%</i>	<i>0.00%</i>	<i>8.49%</i>	<i>89.62%</i>	<i>100.00%</i>	<i>1.89%</i>
	0.09%	0.00%	0.00%	0.00%	0.00%	2.11%	0.04%	0.00%
Total	1,143	5,427	39,179	21,747	228,659	4,492	300,647	67,496
	0.38%	1.81%	13.03%	7.23%	76.06%	1.49%	100.00%	22.45%
	<i>0.38%</i>	<i>1.81%</i>	<i>13.03%</i>	<i>7.23%</i>	<i>76.06%</i>	<i>1.49%</i>	<i>100.00%</i>	<i>22.45%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

192

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

Substantial numbers of women and minorities are enrolled in extramural Phase III research protocols reported in FY2005. More females (277,315 or 59.5%) than males (183,918 or 39.5%) are enrolled in aggregate extramural Phase III research protocols. More minority females (77,657 or 55.7%) than minority males (59,212 or 42.5%) are enrolled in aggregate extramural Phase III research protocols.

Minority:

Approximately 30% (139,456) of participants in aggregate extramural Phase III research (465,956) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 76% following the 1977 OMB standards and 55.75% following the 1997 OMB standards. Largest identified racial minority group is Black at 13% following the 1977 OMB standards and 30% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.4%. According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.3%.

Ethnicity:

6% 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 is White at 37.8%
Smallest identified racial group is Asian at 0.4%
Of the 9,890 participants, 59.4% are women and 40.4% are men.
7.2% of participants identified as Hispanic according to the 1977 OMB standards.

Table 6A. Aggregate Enrollment Data for Extramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	119,987	49,235		41.03%
%	47.52%	50.07%		
Males	127,773	46,515		36.40%
%	50.61%	47.30%		
Unknown	4,723	2,587		54.77%
%	1.87%	2.63%		
TOTAL	252,483	98,337	38.95%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 355

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 227			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	1,160	2,620	20,752	138	26,391	1,002	1,602	53,665	47,985	3,070	2,610	53,665
	0.96%	2.16%	17.14%	0.11%	21.80%	0.83%	1.32%	44.33%	39.64%	2.54%	2.16%	44.33%
	2.16%	4.88%	38.67%	0.26%	49.18%	1.87%	2.99%	100.00%	89.42%	5.72%	4.86%	100.00%
	65.72%	44.84%	47.63%	36.80%	43.15%	46.35%	25.91%	44.33%	44.88%	46.17%	34.85%	44.33%
Male	601	3,185	20,291	237	34,505	1,156	2,798	62,773	56,140	3,562	3,071	62,773
	0.50%	2.63%	16.76%	0.20%	28.50%	0.95%	2.31%	51.85%	46.38%	2.94%	2.54%	51.85%
	0.96%	5.07%	32.32%	0.38%	54.97%	1.84%	4.46%	100.00%	89.43%	5.67%	4.89%	100.00%
	34.05%	54.51%	46.58%	63.20%	56.42%	53.47%	45.26%	51.85%	52.51%	53.56%	41.00%	51.85%
Unknown	4	38	2,523	0	266	4	1,782	4,617	2,790	18	1,809	4,617
	0.00%	0.03%	2.08%	0.00%	0.22%	0.00%	1.47%	3.81%	2.30%	0.01%	1.49%	3.81%
	0.09%	0.82%	54.65%	0.00%	5.76%	0.09%	38.60%	100.00%	60.43%	0.39%	39.18%	100.00%
	0.23%	0.65%	5.79%	0.00%	0.43%	0.19%	28.83%	3.81%	2.61%	0.27%	24.15%	3.81%
Total	1,765	5,843	43,566	375	61,162	2,162	6,182	121,055	106,915	6,650	7,490	121,055
	1.46%	4.83%	35.99%	0.31%	50.52%	1.79%	5.11%	100.00%	88.32%	5.49%	6.19%	100.00%
	1.46%	4.83%	35.99%	0.31%	50.52%	1.79%	5.11%	100.00%	88.32%	5.49%	6.19%	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	410	14	130	19	1,404	139	954	3,070	28,030
	6.17%	0.21%	1.95%	5.62%	21.11%	2.09%	14.35%	46.17%	23.15%
	13.36%	0.46%	4.23%	13.67%	45.73%	4.53%	31.07%	100.00%	52.23%
	89.32%	53.85%	38.35%	57.58%	44.60%	41.12%	41.35%	46.17%	47.38%
Male	48	12	209	14	1,740	198	1,341	3,562	28,551
	0.72%	0.18%	3.14%	4.14%	26.17%	2.98%	20.17%	53.56%	23.59%
	1.35%	0.34%	5.87%	7.07%	48.85%	5.56%	37.65%	100.00%	45.48%
	10.46%	46.15%	61.65%	42.42%	55.27%	58.58%	58.13%	53.56%	48.26%
Unknown	1	0	0	0	4	1	12	18	2,585
	0.02%	0.00%	0.00%	0.00%	0.06%	0.02%	0.18%	0.27%	2.14%
	5.56%	0.00%	0.00%	0.00%	22.22%	5.56%	66.67%	100.00%	55.99%
	0.22%	0.00%	0.00%	0.00%	0.13%	0.30%	0.52%	0.27%	4.37%
TOTAL	459	26	339	33	3,148	338	2,307	6,650	59,166
	6.90%	0.39%	5.10%	9.76%	47.34%	5.08%	34.69%	100.00%	48.88%
	6.90%	0.39%	5.10%	9.76%	47.34%	5.08%	34.69%	100.00%	48.88%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	219	1,125	11,852	8,009	44,069	1,048	66,322	21,205
	0.17%	0.86%	9.02%	6.09%	33.53%	0.80%	50.46%	16.13%
	<i>0.33%</i>	<i>1.70%</i>	<i>17.87%</i>	<i>12.08%</i>	<i>66.45%</i>	<i>1.58%</i>	<i>100.00%</i>	<i>31.97%</i>
	47.00%	52.45%	53.87%	55.01%	48.95%	47.14%	50.46%	54.13%
Male	246	1,020	10,149	6,549	45,956	1,080	65,000	17,964
	0.19%	0.78%	7.72%	4.98%	34.97%	0.82%	49.46%	13.67%
	<i>0.38%</i>	<i>1.57%</i>	<i>15.61%</i>	<i>10.08%</i>	<i>70.70%</i>	<i>1.66%</i>	<i>100.00%</i>	<i>27.64%</i>
	52.79%	47.55%	46.13%	44.99%	51.04%	48.58%	49.46%	45.86%
Unknown	1	0	1	0	9	95	106	2
	0.001%	0.00%	0.00%	0.00%	0.01%	0.07%	0.08%	0.00%
	<i>0.94%</i>	<i>0.00%</i>	<i>0.94%</i>	<i>0.00%</i>	<i>8.49%</i>	<i>89.62%</i>	<i>100.00%</i>	<i>1.89%</i>
	0.21%	0.00%	0.00%	0.00%	0.01%	4.27%	0.08%	0.01%
Total	466	2,145	22,002	14,558	90,034	2,223	131,428	39,171
	0.35%	1.63%	16.74%	11.08%	68.50%	1.69%	100.00%	29.80%
	<i>0.35%</i>	<i>1.63%</i>	<i>16.74%</i>	<i>11.08%</i>	<i>68.50%</i>	<i>1.69%</i>	<i>100.00%</i>	<i>29.80%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

128

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:

Excluding sex-specific studies, the number of females (119,987 or 47.5%) exceeds the number of males (127,773 or 50.6%) enrolled in extramural Phase III research protocols. Excluding sex-specific studies, the number of minority females (49,235 or 50.7%) exceeds the number of male (46,515 or 47.3%) enrolled in extramural Phase III research protocols.

Minority:

Approximately 38.9% (98,337) of participants in aggregate extramural Phase III research excluding sex-specific studies (252,483) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 68.5% following the 1977 OMB standards and 50.5% following the 1997 OMB standards. Largest identified racial minority group is Black at 16.7% following the 1977 OMB standards and 36% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 0.4%. According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.3%.

Ethnicity:

5.5% 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 is White at 47.3%

Smallest identified racial group is Asian at 0.4%

Of the 6,650 participants, 46.2% are women and 53.5% are men.

11% of participants identified as Hispanic according to the 1977 OMB standards.

Table 7A. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form

Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	944,924	255,053		26.99%
%	48.69%	62.34%		
Males	980,254	153,341		15.64%
%	50.51%	37.48%		
Unknown	15,375	765		4.98%
%	0.79%	0.19%		
TOTAL	1,940,553	409,159	21.08%	
Total %	100%	100.00%		

Total Number of
Protocols with
Enrollment Data:

1,470

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

Number of Protocols with
Enrollment Data:

737

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	2,851	16,907	26,811	712	434,744	8,502	22,295	512,822	489,123	11,194	12,505	512,822
	0.28%	1.67%	2.64%	0.07%	42.84%	0.84%	2.20%	50.54%	48.06%	1.10%	1.23%	50.39%
	0.56%	3.30%	5.23%	0.14%	84.77%	1.66%	4.35%	100.00%	95.38%	2.18%	2.44%	100.00%
	67.18%	54.16%	55.73%	36.81%	49.73%	83.62%	49.73%	50.54%	50.29%	52.27%	52.95%	50.39%
Male	1,393	14,308	21,296	1,222	439,434	1,665	19,277	498,595	481,658	10,220	9,717	501,595
	0.14%	1.41%	2.10%	0.12%	43.31%	0.16%	1.90%	49.14%	47.33%	1.00%	0.95%	49.29%
	0.28%	2.87%	4.27%	0.25%	88.13%	0.33%	3.87%	100.00%	96.03%	2.04%	1.94%	100.00%
	32.82%	45.84%	44.26%	63.19%	50.27%	16.38%	43.00%	49.14%	49.52%	47.72%	41.15%	49.29%
Unknown	0	0	5	0	11	0	3,263	3,279	1,885	1	1,393	3,279
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.32%	0.32%	0.19%	0.00%	0.14%	0.32%
	0.00%	0.00%	0.15%	0.00%	0.34%	0.00%	99.51%	100.00%	57.49%	0.03%	42.48%	100.00%
	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	7.28%	0.32%	0.19%	0.00%	5.90%	0.32%
Total	4,244	31,215	48,112	1,934	874,189	10,167	44,835	1,014,696	972,666	21,415	23,615	1,017,696
	0.42%	3.08%	4.74%	0.19%	86.15%	1.00%	4.42%	100.00%	95.58%	2.10%	2.32%	100.00%
	0.42%	3.08%	4.74%	0.19%	86.15%	1.00%	4.42%	100.00%	95.58%	2.10%	2.32%	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	13	27	32	22	692	1,317	9,091	11,194
	0.06%	0.13%	0.15%	0.86%	3.23%	6.15%	42.45%	52.27%
	0.12%	0.24%	0.29%	1.67%	6.18%	11.77%	81.21%	100.00%
	54.17%	90.00%	65.31%	95.65%	86.93%	51.37%	50.71%	52.27%
Male	11	3	17	1	104	1,247	8,837	10,220
	0.05%	0.01%	0.08%	0.04%	0.49%	5.82%	41.27%	47.72%
	0.11%	0.03%	0.17%	0.08%	1.02%	12.20%	86.47%	100.00%
	45.83%	10.00%	34.69%	4.35%	13.07%	48.63%	49.29%	47.72%
Unknown	0	0	0	0	0	0	1	1
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%
TOTAL	24	30	49	23	796	2,564	17,929	21,415
	0.11%	0.14%	0.23%	0.90%	3.72%	11.97%	83.72%	100.00%
	0.11%	0.14%	0.23%	0.90%	3.72%	11.97%	83.72%	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**

65,566
6.46%
12.79%
57.31%
48,825
4.81%
9.79%
42.68%
6
0.00%
0.18%
0.01%
114,397
11.27%
11.27%
100.00%

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	8,753	116,151	34,208	30,375	225,228	17,387	432,102	189,487
	0.95%	12.59%	3.71%	3.29%	24.41%	1.88%	46.82%	20.53%
	<i>2.03%</i>	<i>26.88%</i>	<i>7.92%</i>	<i>7.03%</i>	<i>52.12%</i>	<i>4.02%</i>	<i>100.00%</i>	<i>43.85%</i>
	51.09%	70.54%	49.38%	69.54%	40.04%	26.51%	46.82%	64.28%
Male	8,380	48,478	35,060	12,598	334,876	39,267	478,659	104,516
	0.91%	5.25%	3.80%	1.37%	36.29%	4.25%	51.87%	11.33%
	<i>1.75%</i>	<i>10.13%</i>	<i>7.32%</i>	<i>2.63%</i>	<i>69.96%</i>	<i>8.20%</i>	<i>100.00%</i>	<i>21.84%</i>
	48.91%	29.44%	50.61%	28.84%	59.53%	59.88%	51.87%	35.46%
Unknown	1	37	12	709	2,410	8,927	12,096	759
	0.000%	0.00%	0.00%	0.08%	0.26%	0.97%	1.31%	0.08%
	<i>0.01%</i>	<i>0.31%</i>	<i>0.10%</i>	<i>5.86%</i>	<i>19.92%</i>	<i>73.80%</i>	<i>100.00%</i>	<i>6.27%</i>
	0.01%	0.02%	0.02%	1.62%	0.43%	13.61%	1.31%	0.26%
Total	17,134	164,666	69,280	43,682	562,514	65,581	922,857	294,762
	1.86%	17.84%	7.51%	4.73%	60.95%	7.11%	100.00%	31.94%
	<i>1.86%</i>	<i>17.84%</i>	<i>7.51%</i>	<i>4.73%</i>	<i>60.95%</i>	<i>7.11%</i>	<i>100.00%</i>	<i>31.94%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data: 733

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

More males (980,254 or 50.5%) than females (944,924 or 48.7%) are enrolled in aggregate intramural research protocols.

In contrast, more minority females (255,053 or 62.3%) than minority males (153,341 or 37.5%) are enrolled in aggregate intramural research protocols.

Minority:

Approximately 21% (409,159) of participants in aggregate intramural research (1,940,553) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 61% following the 1977 OMB standards and 86.2% following the 1997 OMB standards.

Largest identified racial minority group is Asian/Pacific Islander at 17.8% following the 1977 OMB standards.

Largest identified racial minority group is Black at 4.7% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0.9%.

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.2%.

Ethnicity:

2.1% 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 is Unknown/Other at 83.72%

Smallest identified racial group is American Indian/Alaskan Native at 0.1%

Of the 21,415 participants, 52.3% are women and 47.7% are men.

4.7% of participants identified as Hispanic according to the 1977 OMB standards.

Table 8A. Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	679,277	135,432		19.94%
%	41.82%	46.51%		
Males	929,621	154,995		16.67%
%	57.23%	53.23%		
Unknown	15,375	765		4.98%
%	0.95%	0.26%		
TOTAL	1,624,273	291,192	17.93%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 1,240

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 594			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	1,579	15,435	24,797	675	309,106	1,737	15,099	368,428	352,745	7,770	7,913	368,428
	0.21%	2.07%	3.32%	0.09%	41.41%	0.23%	2.02%	49.36%	41.67%	0.92%	0.93%	43.53%
	0.43%	4.19%	6.73%	0.18%	83.90%	0.47%	4.10%	100.00%	95.74%	2.11%	2.15%	100.00%
	53.15%	47.30%	54.21%	35.64%	49.66%	51.06%	40.48%	49.36%	43.56%	43.62%	41.96%	43.53%
Male	1,392	17,198	20,940	1,219	313,382	1,665	18,936	374,732	455,138	10,042	9,552	474,732
	0.19%	2.30%	2.81%	0.16%	41.98%	0.22%	2.54%	50.20%	53.77%	1.19%	1.13%	56.09%
	0.37%	4.59%	5.59%	0.33%	83.63%	0.44%	5.05%	100.00%	95.87%	2.12%	2.01%	100.00%
	46.85%	52.70%	45.78%	64.36%	50.34%	48.94%	50.77%	50.20%	56.21%	56.37%	50.65%	56.09%
Unknown	0	0	5	0	11	0	3,263	3,279	1,885	1	1,393	3,279
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.44%	0.44%	0.22%	0.00%	0.16%	0.39%
	0.00%	0.00%	0.15%	0.00%	0.34%	0.00%	99.51%	100.00%	57.49%	0.03%	42.48%	100.00%
	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	8.75%	0.44%	0.23%	0.01%	7.39%	0.39%
Total	2,971	32,633	45,742	1,894	622,499	3,402	37,298	746,439	809,768	17,813	18,858	846,439
	0.40%	4.37%	6.13%	0.25%	83.40%	0.46%	5.00%	100.00%	95.67%	2.10%	2.23%	100.00%
	0.40%	4.37%	6.13%	0.25%	83.40%	0.46%	5.00%	100.00%	95.67%	2.10%	2.23%	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	7	2	9	1	94	1,294	6,363	7,770	50,680
	0.04%	0.01%	0.05%	0.04%	0.53%	7.26%	35.72%	43.62%	6.79%
	0.09%	0.03%	0.12%	0.08%	1.21%	16.65%	81.89%	100.00%	13.76%
	38.89%	40.00%	34.62%	50.00%	47.47%	50.92%	42.36%	43.62%	49.75%
Male	11	3	17	1	104	1,247	8,659	10,042	51,177
	0.06%	0.02%	0.10%	0.04%	0.58%	7.00%	48.61%	56.37%	6.86%
	0.11%	0.03%	0.17%	0.08%	1.04%	12.42%	86.23%	100.00%	13.66%
	61.11%	60.00%	65.38%	50.00%	52.53%	49.08%	57.64%	56.37%	50.24%
Unknown	0	0	0	0	0	0	1	1	6
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	0.18%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.01%
TOTAL	18	5	26	2	198	2,541	15,023	17,813	101,863
	0.10%	0.03%	0.15%	0.08%	1.11%	14.26%	84.34%	100.00%	13.65%
	0.10%	0.03%	0.15%	0.08%	1.11%	14.26%	84.34%	100.00%	13.65%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	8,739	39,190	29,011	7,812	212,728	13,369	310,849	84,752
	1.12%	5.04%	3.73%	1.00%	27.35%	1.72%	39.96%	10.90%
	<i>2.81%</i>	<i>12.61%</i>	<i>9.33%</i>	<i>2.51%</i>	<i>68.43%</i>	<i>4.30%</i>	<i>100.00%</i>	<i>27.26%</i>
	51.05%	44.69%	45.75%	37.02%	38.73%	34.05%	39.96%	44.76%
Male	8,379	48,471	34,386	12,582	334,104	16,967	454,889	103,818
	1.08%	6.23%	4.42%	1.62%	42.95%	2.18%	58.48%	13.35%
	<i>1.84%</i>	<i>10.66%</i>	<i>7.56%</i>	<i>2.77%</i>	<i>73.45%</i>	<i>3.73%</i>	<i>100.00%</i>	<i>22.82%</i>
	48.95%	55.27%	54.23%	59.62%	60.83%	43.21%	58.48%	54.83%
Unknown	1	37	12	709	2,410	8,927	12,096	759
	0.000%	0.00%	0.00%	0.09%	0.31%	1.15%	1.56%	0.10%
	<i>0.01%</i>	<i>0.31%</i>	<i>0.10%</i>	<i>5.86%</i>	<i>19.92%</i>	<i>73.80%</i>	<i>100.00%</i>	<i>6.27%</i>
	0.01%	0.04%	0.02%	3.36%	0.44%	22.74%	1.56%	0.40%
Total	17,119	87,698	63,409	21,103	549,242	39,263	777,834	189,329
	2.20%	11.27%	8.15%	2.71%	70.61%	5.05%	100.00%	24.34%
	<i>2.20%</i>	<i>11.27%</i>	<i>8.15%</i>	<i>2.71%</i>	<i>70.61%</i>	<i>5.05%</i>	<i>100.00%</i>	<i>24.34%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

646

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

Excluding sex-specific studies, the number of males (929,621 or 57.2%) exceeds the number of females (679,277 or 41.8%) enrolled in intramural research protocols. Excluding sex-specific studies, the number of minority males (154,995 or 53.2%) exceeds the number of females (135,432 or 47.5%) enrolled in intramural research protocols.

Minority:

Approximately 18% (291,192) of participants in aggregate intramural research excluding sex-specific studies (1,624,273) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 70.6% following the 1977 OMB standards and 83.4% following the 1997 OMB standards. Largest identified racial minority group is Asian/Pacific Islander at 11.3% following the 1977 OMB standards. Largest identified racial minority group is Blacks at 6.1% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 2.2%. According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.3%.

Ethnicity:

2.1% 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 is Unknown/Other at 84.3%

Smallest identified racial group is Asian at 0.10%

Of the 17,813 participants, 43.6% are women and 56.4% are men.

2.7% of participants identified as Hispanic according to the 1977 OMB standards.

Table 9A. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	13,662	7,358		53.86%
%	50.52%	49.87%		
Males	13,382	7,377		55.13%
%	49.48%	50.00%		
Unknown	0	0		0%
%	0.00%	0.00%		
TOTAL	27,044	14,753	54.55%	
Total %	100%	100.00%		

Total Number of
Protocols with
Enrollment Data:

36

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 18			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	8	89	483	1	5,166	265	424	6,436	5,746	286	404	6,436
	0.07%	0.78%	4.24%	0.01%	45.31%	2.32%	3.72%	56.45%	50.39%	2.51%	3.54%	56.45%
	0.12%	1.38%	7.50%	0.02%	80.27%	4.12%	6.59%	100.00%	89.28%	4.44%	6.28%	100.00%
	40.00%	45.41%	65.36%	100.00%	56.94%	55.44%	47.37%	56.45%	57.31%	56.41%	46.49%	56.45%
Male	12	107	256	0	3,907	213	471	4,966	4,280	221	465	4,966
	0.11%	0.94%	2.25%	0.00%	34.27%	1.87%	4.13%	43.55%	37.54%	1.94%	4.08%	43.55%
	0.24%	2.15%	5.16%	0.00%	78.67%	4.29%	9.48%	100.00%	86.19%	4.45%	9.36%	100.00%
	60.00%	54.59%	34.64%	0.00%	43.06%	44.56%	52.63%	43.55%	42.69%	43.59%	53.51%	43.55%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	20	196	739	1	9,073	478	895	11,402	10,026	507	869	11,402
	0.18%	1.72%	6.48%	0.01%	79.57%	4.19%	7.85%	100.00%	87.93%	4.45%	7.62%	100.00%
	0.18%	1.72%	6.48%	0.01%	79.57%	4.19%	7.85%	100.00%	87.93%	4.45%	7.62%	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	0	0	0	0	0	0	286	286	1,132
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.41%	56.41%	9.93%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.59%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.41%	56.41%	58.32%
Male	0	0	0	0	0	0	221	221	809
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.59%	43.59%	7.10%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	16.29%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.59%	43.59%	41.68%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	0	507	507	1,941
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.02%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.02%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	126	5,993	75	32	995	5	7,226	6,226
	0.81%	38.31%	0.48%	0.20%	6.36%	0.03%	46.20%	39.80%
	<i>1.74%</i>	<i>82.94%</i>	<i>1.04%</i>	<i>0.44%</i>	<i>13.77%</i>	<i>0.07%</i>	<i>100.00%</i>	<i>86.16%</i>
	71.59%	48.67%	33.63%	39.02%	35.12%	33.33%	46.20%	48.66%
Male	50	6,320	148	50	1,838	10	8,416	6,568
	0.32%	40.40%	0.95%	0.32%	11.75%	0.06%	53.80%	41.99%
	<i>0.59%</i>	<i>75.10%</i>	<i>1.76%</i>	<i>0.59%</i>	<i>21.84%</i>	<i>0.12%</i>	<i>100.00%</i>	<i>78.04%</i>
	28.41%	51.33%	66.37%	60.98%	64.88%	66.67%	53.80%	51.34%
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	176	12,313	223	82	2,833	15	15,642	12,794
	1.13%	78.72%	1.43%	0.52%	18.11%	0.10%	100.00%	81.79%
	<i>1.13%</i>	<i>78.72%</i>	<i>1.43%</i>	<i>0.52%</i>	<i>18.11%</i>	<i>0.10%</i>	<i>100.00%</i>	<i>81.79%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

18

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:

Substantial numbers of women and minorities are enrolled in intramural Phase III research protocols reported in FY2005.

More males (13,382 or 49.4%) than females (13,662 or 50.5%) are enrolled in aggregate intramural Phase III research protocols.

More minority males (7,377 or 50%) than minority females (7,358 or 49.9%) are enrolled in aggregate intramural Phase III research protocols.

Minority:

Approximately 54.5% (14,735) of participants in aggregate intramural Phase III research (27,044) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 18% following the 1977 OMB standards.

Largest identified racial minority group is Asian/Pacific Islander at 78.7% following the 1977 OMB standards.

Largest identified racial minority group is Black at 79.6% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is Hispanic at 0.5%.

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.1%.

Ethnicity:

4.5% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.

For participants reporting ethnicity as Hispanic/Latino:

All participants identified their racial category as Unknown/Other (100%)

Of the 507 participants, 56.4% are women and 43.6% are men.

0.5% of participants identified as Hispanic according to the 1977 OMB standards.

Table 10A. Aggregate Enrollment Data for Intramural Phase III Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	13,661	7,358		53.86%
%	50.60%	49.97%		
Males	13,336	7,368		55.25%
%	49.40%	50.03%		
Unknown	0	0		0%
%	0.00%	0.00%		
TOTAL	26,997	14,726	54.55%	
Total %	100%	100.00%		

Total Number of
Protocols with
Enrollment Data:

31

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 14			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	8	89	483	1	5,165	265	424	6,435	5,745	286	404	6,435
	0.07%	0.78%	4.24%	0.01%	45.39%	2.33%	3.73%	56.55%	50.48%	2.51%	3.55%	56.55%
	0.12%	1.38%	7.51%	0.02%	80.26%	4.12%	6.59%	100.00%	89.28%	4.44%	6.28%	100.00%
	40.00%	45.41%	65.36%	100.00%	57.05%	55.44%	47.48%	56.55%	57.42%	56.52%	46.54%	56.55%
Male	12	107	256	0	3,888	213	469	4,945	4,261	220	464	4,945
	0.11%	0.94%	2.25%	0.00%	34.17%	1.87%	4.12%	43.45%	37.44%	1.93%	4.08%	43.45%
	0.24%	2.16%	5.18%	0.00%	78.62%	4.31%	9.48%	100.00%	86.17%	4.45%	9.38%	100.00%
	60.00%	54.59%	34.64%	0.00%	42.95%	44.56%	52.52%	43.45%	42.58%	43.48%	53.46%	43.45%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	20	196	739	1	9,053	478	893	11,380	10,006	506	868	11,380
	0.18%	1.72%	6.49%	0.01%	79.55%	4.20%	7.85%	100.00%	87.93%	4.45%	7.63%	100.00%
	0.18%	1.72%	6.49%	0.01%	79.55%	4.20%	7.85%	100.00%	87.93%	4.45%	7.63%	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	286	286	1,132
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.52%	56.52%	9.95%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.59%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.52%	56.52%	58.35%
Male	0	0	0	0	0	0	220	220	808
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.48%	43.48%	7.10%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	16.34%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.48%	43.48%	41.65%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	0	506	506	1,940
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.05%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.05%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	126	5,993	75	32	995	5	7,226	6,226
	0.81%	38.37%	0.48%	0.20%	6.37%	0.03%	46.27%	39.87%
	<i>1.74%</i>	<i>82.94%</i>	<i>1.04%</i>	<i>0.44%</i>	<i>13.77%</i>	<i>0.07%</i>	<i>100.00%</i>	<i>86.16%</i>
	72.00%	48.68%	34.25%	39.51%	35.33%	33.33%	46.27%	48.69%
Male	49	6,318	144	49	1,821	10	8,391	6,560
	0.31%	40.46%	0.92%	0.31%	11.66%	0.06%	53.73%	42.01%
	<i>0.58%</i>	<i>75.29%</i>	<i>1.72%</i>	<i>0.58%</i>	<i>21.70%</i>	<i>0.12%</i>	<i>100.00%</i>	<i>78.18%</i>
	28.00%	51.32%	65.75%	60.49%	64.67%	66.67%	53.73%	51.31%
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	175	12,311	219	81	2,816	15	15,617	12,786
	1.12%	78.83%	1.40%	0.52%	18.03%	0.10%	100.00%	81.87%
	<i>1.12%</i>	<i>78.83%</i>	<i>1.40%</i>	<i>0.52%</i>	<i>18.03%</i>	<i>0.10%</i>	<i>100.00%</i>	<i>81.87%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

17

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

Excluding sex-specific studies, the number of females (13,661 or 50.6%) exceeds the number of males (13,336 or 49.4%) enrolled in intramural Phase III research protocols.
Excluding sex-specific studies, the number of minority males (7,368 or 5%) exceeds the number of females (7,358 or 49.9%) enrolled in intramural Phase III research protocols.

Minority:

Approximately 54.5% (14,726) of participants in aggregate intramural Phase III research excluding sex-specific studies (26,997) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 18% following the 1977 OMB standards and 79.5% following the 1997 OMB standards.
Largest identified racial minority group is Asian/Pacific Islander at 78.8% following the 1977 OMB standards.
Largest identified racial minority group is Black at 6.5% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is Hispanic at 0.5%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.01%.

Ethnicity:

4.5% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.

For participants reporting ethnicity as Hispanic/Latino:

All participants identified their racial category as Unknown/Other (100%)

Of the 506 participants, 56.5% are women and 43.5% are men.

0.52% of participants identified as Hispanic according to the 1977 OMB standards.

Table 11A. DOMESTIC Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	7,887,209	2,239,359		28.39%
%	62.25%	64.56%		
Males	4,515,242	1,197,772		26.53%
%	35.64%	34.53%		
Unknown	267,407	31,733		11.87%
%	2.11%	0.91%		
TOTAL	12,669,858	3,468,864	27.38%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:

9,862

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 8,126			
	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	268,433	377,242	796,332	25,420	4,727,660	99,879	633,550	6,928,516	5,838,120	472,003	618,393	6,928,516
	2.47%	3.47%	7.32%	0.23%	43.44%	0.92%	5.82%	63.66%	53.64%	4.34%	5.68%	63.66%
	3.87%	5.44%	11.49%	0.37%	68.23%	1.44%	9.14%	100.00%	84.26%	6.81%	8.93%	100.00%
	92.23%	57.51%	64.59%	59.13%	63.16%	60.87%	62.68%	63.66%	64.01%	65.45%	59.37%	63.66%
Male	21,948	272,478	420,262	16,674	2,613,499	63,121	294,813	3,702,795	3,119,173	242,408	341,214	3,702,795
	0.20%	2.50%	3.86%	0.15%	24.01%	0.58%	2.71%	34.02%	28.66%	2.23%	3.14%	34.02%
	0.59%	7.36%	11.35%	0.45%	70.58%	1.70%	7.96%	100.00%	84.24%	6.55%	9.22%	100.00%
	7.54%	41.54%	34.09%	38.78%	34.92%	38.47%	29.17%	34.02%	34.20%	33.61%	32.76%	34.02%
Unknown	663	6,239	16,363	899	144,034	1,096	82,367	251,661	163,000	6,727	81,934	251,661
	0.01%	0.06%	0.15%	0.01%	1.32%	0.01%	0.76%	2.31%	1.50%	0.06%	0.75%	2.31%
	0.26%	2.48%	6.50%	0.36%	57.23%	0.44%	32.73%	100.00%	64.77%	2.67%	32.56%	100.00%
	0.23%	0.95%	1.33%	2.09%	1.92%	0.67%	8.15%	2.31%	1.79%	0.93%	7.87%	2.31%
Total	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
	2.67%	6.03%	11.33%	0.40%	68.78%	1.51%	9.29%	100.00%	83.80%	6.63%	9.57%	100.00%
	2.67%	6.03%	11.33%	0.40%	68.78%	1.51%	9.29%	100.00%	83.80%	6.63%	9.57%	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	17,785	5,691	12,143	1,273	245,474	21,254	168,383	472,003	1,981,163
	2.47%	0.79%	1.68%	3.49%	34.04%	2.95%	23.35%	65.45%	18.20%
	3.77%	1.21%	2.57%	5.99%	52.01%	4.50%	35.67%	100.00%	28.59%
	80.63%	72.87%	62.98%	64.26%	67.68%	58.23%	62.18%	65.45%	65.59%
Male	4,182	2,058	6,978	659	114,174	14,501	99,856	242,408	1,008,513
	0.58%	0.29%	0.97%	1.81%	15.83%	2.01%	13.85%	33.61%	9.27%
	1.73%	0.85%	2.88%	4.54%	47.10%	5.98%	41.19%	100.00%	27.24%
	18.96%	26.35%	36.19%	33.27%	31.48%	39.73%	36.87%	33.61%	33.39%
Unknown	90	61	161	49	3,059	748	2,559	6,727	30,878
	0.01%	0.01%	0.02%	0.13%	0.42%	0.10%	0.35%	0.93%	0.28%
	1.34%	0.91%	2.39%	6.55%	45.47%	11.12%	38.04%	100.00%	12.27%
	0.41%	0.78%	0.83%	2.47%	0.84%	2.05%	0.94%	0.93%	1.02%
TOTAL	22,057	7,810	19,282	1,981	362,707	36,503	270,798	721,138	3,020,554
	3.06%	1.08%	2.67%	5.43%	50.30%	5.06%	37.55%	100.00%	27.75%
	3.06%	1.08%	2.67%	5.43%	50.30%	5.06%	37.55%	100.00%	27.75%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	11,837	47,628	120,247	78,484	668,855	31,642	958,693	258,196
	0.66%	2.67%	6.73%	4.39%	37.43%	1.77%	53.65%	14.45%
	<i>1.23%</i>	<i>4.97%</i>	<i>12.54%</i>	<i>8.19%</i>	<i>69.77%</i>	<i>3.30%</i>	<i>100.00%</i>	<i>26.93%</i>
	52.90%	53.44%	57.13%	62.12%	53.71%	33.94%	53.65%	57.59%
Male	10,422	41,316	89,956	47,565	573,886	49,302	812,447	189,259
	0.58%	2.31%	5.03%	2.66%	32.12%	2.76%	45.47%	10.59%
	<i>1.28%</i>	<i>5.09%</i>	<i>11.07%</i>	<i>5.85%</i>	<i>70.64%</i>	<i>6.07%</i>	<i>100.00%</i>	<i>23.29%</i>
	46.58%	46.36%	42.74%	37.65%	46.08%	52.88%	45.47%	42.22%
Unknown	116	175	262	302	2,596	12,295	15,746	855
	0.006%	0.01%	0.01%	0.02%	0.15%	0.69%	0.88%	0.05%
	<i>0.74%</i>	<i>1.11%</i>	<i>1.66%</i>	<i>1.92%</i>	<i>16.49%</i>	<i>78.08%</i>	<i>100.00%</i>	<i>5.43%</i>
	0.52%	0.20%	0.12%	0.24%	0.21%	13.19%	0.88%	0.19%
Total	22,375	89,119	210,465	126,351	1,245,337	93,239	1,786,886	448,310
	1.25%	4.99%	11.78%	7.07%	69.69%	5.22%	100.00%	25.09%
	<i>1.25%</i>	<i>4.99%</i>	<i>11.78%</i>	<i>7.07%</i>	<i>69.69%</i>	<i>5.22%</i>	<i>100.00%</i>	<i>25.09%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data: 1,736

Legend

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

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

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

Data Table Comments:

Sex/Gender:

More females (7,887,209 or 62.3%) than males (4,515,242 or 35.6%) are enrolled in aggregate domestic extramural and intramural research protocols.
More minority females (2,239,359 or 65%) than minority males (1,197,772 or 34.5%) are enrolled in aggregate domestic extramural and intramural research protocols.

Minority:

Approximately 27.3% (3,468,864) of participants in aggregate domestic extramural and intramural research (12,669,858) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 69.7% following the 1977 OMB standards and 68.8% following the 1997 OMB standards.
Largest identified racial minority group is Black at 11.8% following the 1977 OMB standards and 11.3% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 1.3%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.4%.

Ethnicity:

6.6% 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 is White at 50.3%

Smallest identified racial group is Asian at 1.08%

Of the 721,138 participants, 64.5% are women and 33.6% are men.

7% of participants identified as Hispanic according to the 1977 OMB standards.

Table 12A. DOMESTIC Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	7,129,143	2,112,671		29.63%
%	64.63%	65.29%		
Males	3,646,098	1,091,370		29.93%
%	33.05%	33.73%		
Unknown	255,276	31,711		12.42%
%	2.31%	0.98%		
TOTAL	11,030,517	3,235,752	29.33%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:

8,463

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 7,435			
	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	265,582	369,568	772,181	24,715	4,338,645	92,764	614,305	6,477,760	5,405,237	464,086	608,437	6,477,760
	2.66%	3.70%	7.73%	0.25%	43.43%	0.93%	6.15%	64.85%	54.11%	4.65%	6.09%	64.85%
	4.10%	5.71%	11.92%	0.38%	66.98%	1.43%	9.48%	100.00%	83.44%	7.16%	9.39%	100.00%
	92.60%	57.69%	64.89%	60.18%	64.71%	59.24%	63.33%	64.85%	65.43%	65.88%	59.45%	64.85%
Male	20,563	264,803	401,454	15,453	2,221,683	62,743	276,535	3,263,234	2,695,237	233,606	334,391	3,263,234
	0.21%	2.65%	4.02%	0.15%	22.24%	0.63%	2.77%	32.67%	26.98%	2.34%	3.35%	32.67%
	0.63%	8.11%	12.30%	0.47%	68.08%	1.92%	8.47%	100.00%	82.59%	7.16%	10.25%	100.00%
	7.17%	41.34%	33.74%	37.63%	33.14%	40.07%	28.51%	32.67%	32.62%	33.16%	32.67%	32.67%
Unknown	663	6,239	16,358	899	144,026	1,096	79,227	248,508	161,118	6,726	80,664	248,508
	0.01%	0.06%	0.16%	0.01%	1.44%	0.01%	0.79%	2.49%	1.61%	0.07%	0.81%	2.49%
	0.27%	2.51%	6.58%	0.36%	57.96%	0.44%	31.88%	100.00%	64.83%	2.71%	32.46%	100.00%
	0.23%	0.97%	1.37%	2.19%	2.15%	0.70%	8.17%	2.49%	1.95%	0.95%	7.88%	2.49%
Total	286,808	640,610	1,189,993	41,067	6,704,354	156,603	970,067	9,989,502	8,261,592	704,418	1,023,492	9,989,502
	2.87%	6.41%	11.91%	0.41%	67.11%	1.57%	9.71%	100.00%	82.70%	7.05%	10.25%	100.00%
	2.87%	6.41%	11.91%	0.41%	67.11%	1.57%	9.71%	100.00%	82.70%	7.05%	10.25%	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	17,772	5,664	12,111	1,251	244,782	21,222	161,284	464,086	1,930,876
	2.52%	0.80%	1.72%	3.43%	34.75%	3.01%	22.90%	65.88%	19.33%
	3.83%	1.22%	2.61%	5.89%	52.74%	4.57%	34.75%	100.00%	29.81%
	80.66%	72.80%	62.97%	63.89%	67.64%	58.23%	63.23%	65.88%	65.85%
Male	4,171	2,055	6,961	658	114,070	14,475	91,216	233,606	970,302
	0.59%	0.29%	0.99%	1.81%	16.19%	2.05%	12.95%	33.16%	9.71%
	1.79%	0.88%	2.98%	4.55%	48.83%	6.20%	39.05%	100.00%	29.73%
	18.93%	26.41%	36.19%	33.61%	31.52%	39.72%	35.76%	33.16%	33.09%
Unknown	90	61	161	49	3,059	748	2,558	6,726	30,872
	0.01%	0.01%	0.02%	0.13%	0.43%	0.11%	0.36%	0.95%	0.31%
	1.34%	0.91%	2.39%	6.55%	45.48%	11.12%	38.03%	100.00%	12.42%
	0.41%	0.78%	0.84%	2.50%	0.85%	2.05%	1.00%	0.95%	1.05%
TOTAL	22,033	7,780	19,233	1,958	361,911	36,445	255,058	704,418	2,932,050
	3.13%	1.10%	2.73%	5.37%	51.38%	5.17%	36.21%	100.00%	29.35%
	3.13%	1.10%	2.73%	5.37%	51.38%	5.17%	36.21%	100.00%	29.35%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	3,084	39,788	88,897	50,026	450,942	18,646	651,383	181,795
	0.30%	3.82%	8.54%	4.81%	43.32%	1.79%	62.57%	17.46%
	<i>0.47%</i>	<i>6.11%</i>	<i>13.65%</i>	<i>7.68%</i>	<i>69.23%</i>	<i>2.86%</i>	<i>100.00%</i>	<i>27.91%</i>
	58.84%	60.80%	60.85%	57.56%	64.34%	51.12%	62.57%	59.86%
Male	2,042	25,478	56,956	36,592	247,334	14,462	382,864	121,068
	0.20%	2.45%	5.47%	3.52%	23.76%	1.39%	36.78%	11.63%
	<i>0.53%</i>	<i>6.65%</i>	<i>14.88%</i>	<i>9.56%</i>	<i>64.60%</i>	<i>3.78%</i>	<i>100.00%</i>	<i>31.62%</i>
	38.96%	38.93%	38.98%	42.10%	35.29%	39.65%	36.78%	39.86%
Unknown	115	175	250	299	2,561	3,368	6,768	839
	0.011%	0.02%	0.02%	0.03%	0.25%	0.32%	0.65%	0.08%
	<i>1.70%</i>	<i>2.59%</i>	<i>3.69%</i>	<i>4.42%</i>	<i>37.84%</i>	<i>49.76%</i>	<i>100.00%</i>	<i>12.40%</i>
	2.19%	0.27%	0.17%	0.34%	0.37%	9.23%	0.65%	0.28%
Total	5,241	65,441	146,103	86,917	700,837	36,476	1,041,015	303,702
	0.50%	6.29%	14.03%	8.35%	67.32%	3.50%	100.00%	29.17%
	<i>0.50%</i>	<i>6.29%</i>	<i>14.03%</i>	<i>8.35%</i>	<i>67.32%</i>	<i>3.50%</i>	<i>100.00%</i>	<i>29.17%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

1,028

Legend

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

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

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

Data Table Comments:

Sex/Gender:

More females (7,129,143 or 64.6%) than males (3,646,098 or 33%) are enrolled in aggregate domestic extramural research protocols.

More minority females (2,112,671 or 65.3%) than minority males (1,091,370 or 33.7%) are enrolled in aggregate domestic extramural research protocols.

Minority:

Approximately 29.3% (3,235,752) of participants in aggregate domestic extramural research (11,030,517) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 67.3% following the 1977 OMB standards and 67.1% following the 1997 OMB standards.

Largest identified racial minority group is Black at 14.3% following the 1977 OMB standards and 11.9% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 0.5%.

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.4%.

Ethnicity:

7.1% 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 is White at 51.4%

Smallest identified racial group is Asian at 1.1%.

Of the 704,418 participants, 65.8% are women and 33.1% are men.

8.4% of participants identified as Hispanic according to the 1977 OMB standards.

Table 13A. DOMESTIC Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	758,066	126,688		16.71%
%	46.24%	54.35%		
Males	869,144	106,402		12.24%
%	53.02%	45.64%		
Unknown	12,131	22		0.18%
%	0.74%	0.01%		
TOTAL	1,639,341	233,112	14.22%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 1,399

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 691			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	2,851	7,674	24,151	705	389,015	7,115	19,245	450,756	432,883	7,917	9,956	450,756
	0.32%	0.86%	2.70%	0.08%	43.54%	0.80%	2.15%	50.45%	48.45%	0.89%	1.11%	50.45%
	0.63%	1.70%	5.36%	0.16%	86.30%	1.58%	4.27%	100.00%	96.03%	1.76%	2.21%	100.00%
	67.30%	50.00%	56.21%	36.60%	49.82%	94.96%	47.33%	50.45%	50.41%	47.35%	55.16%	50.45%
Male	1,385	7,675	18,808	1,221	391,816	378	18,278	439,561	423,936	8,802	6,823	439,561
	0.16%	0.86%	2.11%	0.14%	43.85%	0.04%	2.05%	49.20%	47.45%	0.99%	0.76%	49.20%
	0.32%	1.75%	4.28%	0.28%	89.14%	0.09%	4.16%	100.00%	96.45%	2.00%	1.55%	100.00%
	32.70%	50.00%	43.78%	63.40%	50.18%	5.04%	44.95%	49.20%	49.37%	52.64%	37.80%	49.20%
Unknown	0	0	5	0	8	0	3,140	3,153	1,882	1	1,270	3,153
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.35%	0.35%	0.21%	0.00%	0.14%	0.35%
	0.00%	0.00%	0.16%	0.00%	0.25%	0.00%	99.59%	100.00%	59.69%	0.03%	40.28%	100.00%
	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	7.72%	0.35%	0.22%	0.01%	7.04%	0.35%
Total	4,236	15,349	42,964	1,926	780,839	7,493	40,663	893,470	858,701	16,720	18,049	893,470
	0.47%	1.72%	4.81%	0.22%	87.39%	0.84%	4.55%	100.00%	96.11%	1.87%	2.02%	100.00%
	0.47%	1.72%	4.81%	0.22%	87.39%	0.84%	4.55%	100.00%	96.11%	1.87%	2.02%	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	13	27	32	22	692	32	7,099	7,917	50,287
	0.08%	0.16%	0.19%	0.13%	4.14%	0.19%	42.46%	47.35%	5.63%
	0.16%	0.34%	0.40%	0.28%	8.74%	0.40%	89.67%	100.00%	11.16%
	54.17%	90.00%	65.31%	95.65%	86.93%	55.17%	45.10%	47.35%	56.82%
Male	11	3	17	1	104	26	8,640	8,802	38,211
	0.07%	0.02%	0.10%	0.01%	0.62%	0.16%	51.67%	52.64%	4.28%
	0.12%	0.03%	0.19%	0.01%	1.18%	0.30%	98.16%	100.00%	8.69%
	45.83%	10.00%	34.69%	4.35%	13.07%	44.83%	54.89%	52.64%	43.17%
Unknown	0	0	0	0	0	0	1	1	6
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	0.19%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.01%	0.01%
TOTAL	24	30	49	23	796	58	15,740	16,720	88,504
	0.14%	0.18%	0.29%	0.14%	4.76%	0.35%	94.14%	100.00%	9.91%
	0.14%	0.18%	0.29%	0.14%	4.76%	0.35%	94.14%	100.00%	9.91%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	8,753	7,840	31,350	28,458	217,913	12,996	307,310	76,401
	1.17%	1.05%	4.20%	3.82%	29.22%	1.74%	41.20%	10.24%
	2.85%	2.55%	10.20%	9.26%	70.91%	4.23%	100.00%	24.86%
	51.09%	33.11%	48.71%	72.17%	40.02%	22.90%	41.20%	52.83%
Male	8,380	15,838	33,000	10,973	326,552	34,840	429,583	68,191
	1.12%	2.12%	4.42%	1.47%	43.78%	4.67%	57.59%	9.14%
	1.95%	3.69%	7.68%	2.55%	76.02%	8.11%	100.00%	15.87%
	48.91%	66.89%	51.27%	27.83%	59.97%	61.38%	57.59%	47.16%
Unknown	1	0	12	3	35	8,927	8,978	16
	0.000%	0.00%	0.00%	0.00%	0.00%	1.20%	1.20%	0.00%
	0.01%	0.00%	0.13%	0.03%	0.39%	99.43%	100.00%	0.18%
	0.01%	0.00%	0.02%	0.01%	0.01%	15.73%	1.20%	0.01%
Total	17,134	23,678	64,362	39,434	544,500	56,763	745,871	144,608
	2.30%	3.17%	8.63%	5.29%	73.00%	7.61%	100.00%	19.39%
	2.30%	3.17%	8.63%	5.29%	73.00%	7.61%	100.00%	19.39%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

708

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

More males (869,144 or 53%) than females (758,066 or 46.2%) are enrolled in aggregate domestic intramural research protocols.
More minority females (126,688 or 54.3%) than minority males (106,402 or 45.6%) are enrolled in aggregate domestic intramural research protocols.

Minority:

Approximately 14.2% (233,112) of participants in aggregate domestic intramural research (1,639,341) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 73% following the 1997 OMB standards and 87.4% following the 1997 OMB standards.
Largest identified racial minority group is Black at 8.6% following the 1977 OMB standards and 4.8% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 2.3%.
According to the 1997 OMB standards, the smallest identified racial minority groups is Hawaiian/Pacific Islander at 0.2%.

Ethnicity:

1.9% 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 is White at 4.8%

Remaining participants identified the racial category of Unknown/Other at 94.1%

Of the 16,720 participants, 47.4% are women and 52.6% are men.

5.3% of participants identified as Hispanic according to the 1977 OMB standards.

Table 14A. DOMESTIC Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	254,207	62,328		24.52%
%	59.99%	57.97%		
Males	167,395	45,137		26.96%
%	39.50%	41.98%		
Unknown	2,176	48		2.21%
%	0.51%	0.04%		
TOTAL	423,778	107,513	25.37%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:

484

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 296			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	1,142	2,266	13,013	205	36,005	1,372	3,642	57,645	48,950	5,266	3,429	57,645
	0.90%	1.79%	10.28%	0.16%	28.44%	1.08%	2.88%	45.54%	38.67%	4.16%	2.71%	45.54%
	1.98%	3.93%	22.57%	0.36%	62.46%	2.38%	6.32%	100.00%	84.92%	9.14%	5.95%	100.00%
	65.07%	47.97%	54.81%	44.47%	42.56%	53.08%	41.69%	45.54%	45.08%	56.83%	39.27%	45.54%
Male	609	2,455	10,708	256	48,320	1,209	3,311	66,868	59,392	3,982	3,494	66,868
	0.48%	1.94%	8.46%	0.20%	38.17%	0.96%	2.62%	52.82%	46.92%	3.15%	2.76%	52.82%
	0.91%	3.67%	16.01%	0.38%	72.26%	1.81%	4.95%	100.00%	88.82%	5.96%	5.23%	100.00%
	34.70%	51.97%	45.11%	55.53%	57.12%	46.77%	37.90%	52.82%	54.69%	42.97%	40.01%	52.82%
Unknown	4	3	19	0	264	4	1,782	2,076	249	18	1,809	2,076
	0.00%	0.00%	0.02%	0.00%	0.21%	0.00%	1.41%	1.64%	0.20%	0.01%	1.43%	1.64%
	0.19%	0.14%	0.92%	0.00%	12.72%	0.19%	85.84%	100.00%	11.99%	0.87%	87.14%	100.00%
	0.23%	0.06%	0.08%	0.00%	0.31%	0.15%	20.40%	1.64%	0.23%	0.19%	20.72%	1.64%
Total	1,755	4,724	23,740	461	84,589	2,585	8,735	126,589	108,591	9,266	8,732	126,589
	1.39%	3.73%	18.75%	0.36%	66.82%	2.04%	6.90%	100.00%	85.78%	7.32%	6.90%	100.00%
	1.39%	3.73%	18.75%	0.36%	66.82%	2.04%	6.90%	100.00%	85.78%	7.32%	6.90%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								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	329	30	234	31	1,858	223	2,561	5,266	22,417
	3.55%	0.32%	2.53%	7.33%	20.05%	2.41%	27.64%	56.83%	17.71%
	6.25%	0.57%	4.44%	13.90%	35.28%	4.23%	48.63%	100.00%	38.89%
	88.68%	71.43%	52.47%	68.89%	50.72%	52.72%	59.89%	56.83%	54.40%
Male	41	12	212	14	1,801	199	1,703	3,982	18,741
	0.44%	0.13%	2.29%	3.31%	19.44%	2.15%	18.38%	42.97%	14.80%
	1.03%	0.30%	5.32%	7.04%	45.23%	5.00%	42.77%	100.00%	28.03%
	11.05%	28.57%	47.53%	31.11%	49.17%	47.04%	39.83%	42.97%	45.48%
Unknown	1	0	0	0	4	1	12	18	46
	0.01%	0.00%	0.00%	0.00%	0.04%	0.01%	0.13%	0.19%	0.04%
	5.56%	0.00%	0.00%	0.00%	22.22%	5.56%	66.67%	100.00%	2.22%
	0.27%	0.00%	0.00%	0.00%	0.11%	0.24%	0.28%	0.19%	0.11%
TOTAL	371	42	446	45	3,663	423	4,276	9,266	41,204
	4.00%	0.45%	4.81%	10.64%	39.53%	4.57%	46.15%	100.00%	32.55%
	4.00%	0.45%	4.81%	10.64%	39.53%	4.57%	46.15%	100.00%	32.55%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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	759	3,934	23,347	11,871	154,032	2,619	196,562	39,911
	0.26%	1.32%	7.86%	3.99%	51.83%	0.88%	66.14%	13.43%
	<i>0.39%</i>	<i>2.00%</i>	<i>11.88%</i>	<i>6.04%</i>	<i>78.36%</i>	<i>1.33%</i>	<i>100.00%</i>	<i>20.30%</i>
	66.40%	72.53%	59.59%	57.73%	68.03%	58.49%	66.14%	60.19%
Male	383	1,490	15,830	8,693	72,361	1,770	100,527	26,396
	0.13%	0.50%	5.33%	2.93%	24.35%	0.60%	33.83%	8.88%
	<i>0.38%</i>	<i>1.48%</i>	<i>15.75%</i>	<i>8.65%</i>	<i>71.98%</i>	<i>1.76%</i>	<i>100.00%</i>	<i>26.26%</i>
	33.51%	27.47%	40.41%	42.27%	31.96%	39.53%	33.83%	39.81%
Unknown	1	0	1	0	9	89	100	2
	0.000%	0.00%	0.00%	0.00%	0.00%	0.03%	0.03%	0.00%
	<i>1.00%</i>	<i>0.00%</i>	<i>1.00%</i>	<i>0.00%</i>	<i>9.00%</i>	<i>89.00%</i>	<i>100.00%</i>	<i>2.00%</i>
	0.09%	0.00%	0.00%	0.00%	0.00%	1.99%	0.03%	0.00%
Total	1,143	5,424	39,178	20,564	226,402	4,478	297,189	66,309
	0.38%	1.83%	13.18%	6.92%	76.18%	1.51%	100.00%	22.31%
	<i>0.38%</i>	<i>1.83%</i>	<i>13.18%</i>	<i>6.92%</i>	<i>76.18%</i>	<i>1.51%</i>	<i>100.00%</i>	<i>22.31%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

188

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

Substantial numbers of women and minorities are enrolled in foreign extramural Phase III research protocols reported in FY2005. More females (254,207 or 59.9%) than males (167,395 or 39.5%) are enrolled in aggregate domestic extramural Phase III research protocols. More minority females (62,328 or 57.9%) than minority males (45,137 or 4%) are enrolled in aggregate domestic extramural Phase III research protocols.

Minority:

Approximately 25.4% (107,513) of participants in aggregate domestic extramural Phase III research (423,778) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 76.2% following the 1977 OMB standards and 66.8% following the 1997 OMB standards. Largest identified racial minority group is Black at 13.2% following the 1977 OMB standards and 18.7% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 0.4%. According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0.4%.

Ethnicity:

7.3% 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 is White at 39.5%
Smallest identified racial group is Asian at 0.5%
Of the 9,266 participants, 56.8% are women and 43% are men.
6.9% of participants identified as Hispanic according to the 1977 OMB standards.

Table 15A. DOMESTIC Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	7,382	1,336		18.10%
%	52.27%	55.74%		
Males	6,742	1,061		15.74%
%	47.73%	44.26%		
Unknown	0	0		0%
%	0.00%	0.00%		
TOTAL	14,124	2,397	16.97%	
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: 16			
	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	8	89	431	1	5,166	265	166	6,126	5,694	286	146	6,126
	0.07%	0.83%	4.02%	0.01%	48.14%	2.47%	1.55%	57.09%	53.06%	2.67%	1.36%	57.09%
	0.13%	1.45%	7.04%	0.02%	84.33%	4.33%	2.71%	100.00%	92.95%	4.67%	2.38%	100.00%
	40.00%	45.41%	66.31%	100.00%	56.94%	55.44%	53.04%	57.09%	57.30%	56.41%	50.87%	57.09%
Male	12	107	219	0	3,907	213	147	4,605	4,243	221	141	4,605
	0.11%	1.00%	2.04%	0.00%	36.41%	1.98%	1.37%	42.91%	39.54%	2.06%	1.31%	42.91%
	0.26%	2.32%	4.76%	0.00%	84.84%	4.63%	3.19%	100.00%	92.14%	4.80%	3.06%	100.00%
	60.00%	54.59%	33.69%	0.00%	43.06%	44.56%	46.96%	42.91%	42.70%	43.59%	49.13%	42.91%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	20	196	650	1	9,073	478	313	10,731	9,937	507	287	10,731
	0.19%	1.83%	6.06%	0.01%	84.55%	4.45%	2.92%	100.00%	92.60%	4.72%	2.67%	100.00%
	0.19%	1.83%	6.06%	0.01%	84.55%	4.45%	2.92%	100.00%	92.60%	4.72%	2.67%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

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

	Total of All Subjects by Race								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	286	286	1,080
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.41%	56.41%	10.06%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.63%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	56.41%	56.41%	58.32%
Male	0	0	0	0	0	0	221	221	772
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.59%	43.59%	7.19%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	16.76%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	43.59%	43.59%	41.68%
Unknown	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	0	507	507	1,852
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.26%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	17.26%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%

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	126	23	75	32	995	5	1,256	256
	3.71%	0.68%	2.21%	0.94%	29.33%	0.15%	37.02%	7.54%
	<i>10.03%</i>	<i>1.83%</i>	<i>5.97%</i>	<i>2.55%</i>	<i>79.22%</i>	<i>0.40%</i>	<i>100.00%</i>	<i>20.38%</i>
	71.59%	35.94%	33.63%	39.02%	35.12%	33.33%	37.02%	46.97%
Male	50	41	148	50	1,838	10	2,137	289
	1.47%	1.21%	4.36%	1.47%	54.17%	0.29%	62.98%	8.52%
	<i>2.34%</i>	<i>1.92%</i>	<i>6.93%</i>	<i>2.34%</i>	<i>86.01%</i>	<i>0.47%</i>	<i>100.00%</i>	<i>13.52%</i>
	28.41%	64.06%	66.37%	60.98%	64.88%	66.67%	62.98%	53.03%
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	176	64	223	82	2,833	15	3,393	545
	5.19%	1.89%	6.57%	2.42%	83.50%	0.44%	100.00%	16.06%
	<i>5.19%</i>	<i>1.89%</i>	<i>6.57%</i>	<i>2.42%</i>	<i>83.50%</i>	<i>0.44%</i>	<i>100.00%</i>	<i>16.06%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols
with Enrollment Data:

17

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

Substantial numbers of women and minorities are enrolled in domestic intramural Phase III research protocols reported in FY2005. More females (7,382 or 52.2%) than males (6,742 or 47.7%) are enrolled in aggregate domestic intramural Phase III research protocols. More minority females (1,136 or 55.7%) than minority males (1,061 or 44.3%) are enrolled in aggregate domestic intramural Phase III research protocols.

Minority:

Approximately 17% (2,397) of participants in aggregate domestic intramural Phase III research (14,124) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 83.5% following the 1977 OMB standards and 84.5% following the 1997 OMB standards. Largest identified racial minority group is Black at 6.6% following the 1977 OMB standards and 6.1% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority group is Asian/Pacific Islander at 1.9%. According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at 0.01%.

Ethnicity:

4.7% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards.

For participants reporting ethnicity as Hispanic/Latino:

All participants identified their racial category as Unknown/Other (100%)

Of the 507 participants, 56.4% are women and 43.5% are men.

2.4% of participants identified as Hispanic according to the 1977 OMB standards.

Table 16A. FOREIGN Aggregate Enrollment Data for Extramural and Intramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	1,616,713	1,474,926		91.23%
%	52.96%	53.12%		
Males	1,426,665	1,296,016		90.84%
%	46.73%	46.68%		
Unknown	9,516	5,623		59.09%
%	0.31%	0.20%		
TOTAL	3,052,894	2,776,565	90.95%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data:

371

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 321			
	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	731	1,221,535	66,811	5,070	109,507	9,857	50,097	1,463,608	1,376,467	39,728	47,413	1,463,608
	0.03%	43.18%	2.36%	0.18%	3.87%	0.35%	1.77%	51.74%	48.66%	1.40%	1.68%	51.74%
	0.05%	83.46%	4.56%	0.35%	7.48%	0.67%	3.42%	100.00%	94.05%	2.71%	3.24%	100.00%
	62.43%	51.10%	53.32%	49.26%	58.34%	52.27%	52.73%	51.74%	51.29%	75.24%	51.51%	51.74%
Male	385	1,168,638	54,124	5,153	77,935	8,988	43,503	1,358,726	1,302,146	12,872	43,708	1,358,726
	0.01%	41.31%	1.91%	0.18%	2.76%	0.32%	1.54%	48.03%	46.03%	0.46%	1.55%	48.03%
	0.03%	86.01%	3.98%	0.38%	5.74%	0.66%	3.20%	100.00%	95.84%	0.95%	3.22%	100.00%
	32.88%	48.89%	43.19%	50.06%	41.52%	47.66%	45.79%	48.03%	48.52%	24.38%	47.48%	48.03%
Unknown	55	231	4,370	70	255	12	1,399	6,392	5,258	201	933	6,392
	0.00%	0.01%	0.15%	0.00%	0.01%	0.00%	0.05%	0.23%	0.19%	0.01%	0.03%	0.23%
	0.86%	3.61%	68.37%	1.10%	3.99%	0.19%	21.89%	100.00%	82.26%	3.14%	14.60%	100.00%
	4.70%	0.01%	3.49%	0.68%	0.14%	0.06%	1.47%	0.23%	0.20%	0.38%	1.01%	0.23%
Total	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
	0.04%	84.50%	4.43%	0.36%	6.64%	0.67%	3.36%	100.00%	94.88%	1.87%	3.25%	100.00%
	0.04%	84.50%	4.43%	0.36%	6.64%	0.67%	3.36%	100.00%	94.88%	1.87%	3.25%	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	459	2	81	0	23,191	7,881	8,114	39,728	1,335,309
	0.87%	0.00%	0.15%	0.00%	43.92%	14.93%	15.37%	75.24%	47.21%
	1.16%	0.01%	0.20%	0.00%	58.37%	19.84%	20.42%	100.00%	91.23%
	67.30%	33.33%	49.39%	0.00%	88.65%	53.74%	72.94%	75.24%	51.69%
Male	172	4	83	0	2,830	6,775	3,008	12,872	1,243,126
	0.33%	0.01%	0.16%	0.00%	5.36%	12.83%	5.70%	24.38%	43.95%
	1.34%	0.03%	0.64%	0.00%	21.99%	52.63%	23.37%	100.00%	91.49%
	25.22%	66.67%	50.61%	0.00%	10.82%	46.20%	27.04%	24.38%	48.12%
Unknown	51	0	0	0	140	8	2	201	4,880
	0.10%	0.00%	0.00%	0.00%	0.27%	0.02%	0.00%	0.38%	0.17%
	25.37%	0.00%	0.00%	0.00%	69.65%	3.98%	1.00%	100.00%	76.35%
	7.48%	0.00%	0.00%	0.00%	0.54%	0.05%	0.02%	0.38%	0.19%
TOTAL	682	6	164	0	26,161	14,664	11,124	52,801	2,583,315
	1.29%	0.01%	0.31%	0.00%	49.55%	27.77%	21.07%	100.00%	91.32%
	1.29%	0.01%	0.31%	0.00%	49.55%	27.77%	21.07%	100.00%	91.32%
	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	122,763	12,559	4,295	8,969	4,519	153,105	139,617
	0.00%	54.76%	5.60%	1.92%	4.00%	2.02%	68.30%	62.28%
	<i>0.00%</i>	<i>80.18%</i>	<i>8.20%</i>	<i>2.81%</i>	<i>5.86%</i>	<i>2.95%</i>	<i>100.00%</i>	<i>91.19%</i>
	0.00%	74.19%	65.58%	49.82%	41.23%	49.30%	68.30%	72.25%
Male	0	42,679	6,591	3,620	10,408	4,641	67,939	52,890
	0.00%	19.04%	2.94%	1.61%	4.64%	2.07%	30.31%	23.59%
	<i>0.00%</i>	<i>62.82%</i>	<i>9.70%</i>	<i>5.33%</i>	<i>15.32%</i>	<i>6.83%</i>	<i>100.00%</i>	<i>77.85%</i>
	0.00%	25.79%	34.42%	41.99%	47.85%	50.63%	30.31%	27.37%
Unknown	0	37	0	706	2,375	6	3,124	743
	0.000%	0.02%	0.00%	0.31%	1.06%	0.00%	1.39%	0.33%
	<i>0.00%</i>	<i>1.18%</i>	<i>0.00%</i>	<i>22.60%</i>	<i>76.02%</i>	<i>0.19%</i>	<i>100.00%</i>	<i>23.78%</i>
	0.00%	0.02%	0.00%	8.19%	10.92%	0.07%	1.39%	0.38%
Total	0	165,479	19,150	8,621	21,752	9,166	224,168	193,250
	0.00%	73.82%	8.54%	3.85%	9.70%	4.09%	100.00%	86.21%
	<i>0.00%</i>	<i>73.82%</i>	<i>8.54%</i>	<i>3.85%</i>	<i>9.70%</i>	<i>4.09%</i>	<i>100.00%</i>	<i>86.21%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

50

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/Rthnicity (Column Total)

Data Table Comments:

Sex/Gender:

More females (1,616,713 or 52.9%) than males (1,426,665 or 46.7%) are enrolled in aggregate foreign extramural and intramural research protocols.
More minority females (1,414,926 or 52.9%) than minority males (1,296,016 or 46.7%) are enrolled in aggregate foreign extramural and intramural research protocols.

Minority:

Approximately 91% (2,776,565) of participants in aggregate foreign extramural and intramural research (3,052,894) are classified as U.S. minorities.

Race:

White doesn't rank as top racial category.
Largest identified racial minority group is Asian/Pacific Islander at 73.8% following the 1977 OMB standards.
Largest identified racial minority group is Asians at 84.5% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 0.04% and 0% following the 1997 OMB standards.

Ethnicity:

1.8% 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 is White at 49.5%

Smallest identified racial group is Hawaiian/Pacific Islander at 0%

Of the 52,801 participants, 75.2% are women and 24.4% are men.

3.9% of participants identified as Hispanic according to the 1977 OMB standards.

Table 17A. FOREIGN Aggregate Enrollment Data for Extramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	1,429,855	1,346,564		94.17%
%	51.96%	51.84%		
Males	1,315,555	1,246,081		94.72%
%	47.81%	47.97%		
Unknown	6,272	4,880		77.81%
%	0.23%	0.19%		
TOTAL	2,751,682	2,597,525	94.40%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 300

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 275			
	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	731	1,212,305	64,151	5,063	63,778	8,470	47,044	1,401,542	1,320,227	36,451	44,864	1,401,542
	0.03%	44.83%	2.37%	0.19%	2.36%	0.31%	1.74%	51.82%	48.82%	1.35%	1.66%	51.82%
	0.05%	86.50%	4.58%	0.36%	4.55%	0.60%	3.36%	100.00%	94.20%	2.60%	3.20%	100.00%
	62.85%	51.12%	53.39%	49.23%	67.60%	52.34%	51.80%	51.82%	51.37%	75.77%	51.87%	51.82%
Male	377	1,159,009	51,636	5,152	30,317	7,701	42,500	1,296,692	1,244,424	11,454	40,814	1,296,692
	0.01%	42.85%	1.91%	0.19%	1.12%	0.28%	1.57%	47.95%	46.01%	0.42%	1.51%	47.95%
	0.03%	89.38%	3.98%	0.40%	2.34%	0.59%	3.28%	100.00%	95.97%	0.88%	3.15%	100.00%
	32.42%	48.87%	42.97%	50.09%	32.13%	47.59%	46.80%	47.95%	48.42%	23.81%	47.19%	47.95%
Unknown	55	231	4,370	70	252	12	1,276	6,266	5,255	201	810	6,266
	0.00%	0.01%	0.16%	0.00%	0.01%	0.00%	0.05%	0.23%	0.19%	0.01%	0.03%	0.23%
	0.88%	3.69%	69.74%	1.12%	4.02%	0.19%	20.36%	100.00%	83.87%	3.21%	12.93%	100.00%
	4.73%	0.01%	3.64%	0.68%	0.27%	0.07%	1.40%	0.23%	0.20%	0.42%	0.94%	0.23%
Total	1,163	2,371,545	120,157	10,285	94,347	16,183	90,820	2,704,500	2,569,906	48,106	86,488	2,704,500
	0.04%	87.69%	4.44%	0.38%	3.49%	0.60%	3.36%	100.00%	95.02%	1.78%	3.20%	100.00%
	0.04%	87.69%	4.44%	0.38%	3.49%	0.60%	3.36%	100.00%	95.02%	1.78%	3.20%	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								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	459	2	81	0	23,191	6,596	6,122	36,451	1,320,033
	0.95%	0.00%	0.17%	0.00%	48.21%	13.71%	12.73%	75.77%	48.81%
	1.26%	0.01%	0.22%	0.00%	63.62%	18.10%	16.80%	100.00%	94.18%
	67.30%	33.33%	49.39%	0.00%	88.65%	54.25%	68.52%	75.77%	51.68%
Male	172	4	83	0	2,830	5,554	2,811	11,454	1,229,516
	0.36%	0.01%	0.17%	0.00%	5.88%	11.55%	5.84%	23.81%	45.46%
	1.50%	0.03%	0.72%	0.00%	24.71%	48.49%	24.54%	100.00%	94.82%
	25.22%	66.67%	50.61%	0.00%	10.82%	45.68%	31.46%	23.81%	48.13%
Unknown	51	0	0	0	140	8	2	201	4,880
	0.11%	0.00%	0.00%	0.00%	0.29%	0.02%	0.00%	0.42%	0.18%
	25.37%	0.00%	0.00%	0.00%	69.65%	3.98%	1.00%	100.00%	77.88%
	7.48%	0.00%	0.00%	0.00%	0.54%	0.07%	0.02%	0.42%	0.19%
TOTAL	682	6	164	0	26,161	12,158	8,935	48,106	2,554,429
	1.42%	0.01%	0.34%	0.00%	54.38%	25.27%	18.57%	100.00%	94.45%
	1.42%	0.01%	0.34%	0.00%	54.38%	25.27%	18.57%	100.00%	94.45%
	100.00%	100.00%	100.00%	0.00%	100.00%	100.00%	100.00%	100.00%	100.00%

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	14,452	9,701	2,378	1,654	128	28,313	26,531
	0.00%	30.63%	20.56%	5.04%	3.51%	0.27%	60.01%	56.23%
	<i>0.00%</i>	<i>51.04%</i>	<i>34.26%</i>	<i>8.40%</i>	<i>5.84%</i>	<i>0.45%</i>	<i>100.00%</i>	<i>93.71%</i>
	0.00%	59.01%	68.16%	54.38%	44.25%	36.78%	60.01%	61.56%
Male	0	10,039	4,531	1,995	2,084	214	18,863	16,565
	0.00%	21.28%	9.60%	4.23%	4.42%	0.45%	39.98%	35.11%
	<i>0.00%</i>	<i>53.22%</i>	<i>24.02%</i>	<i>10.58%</i>	<i>11.05%</i>	<i>1.13%</i>	<i>100.00%</i>	<i>87.82%</i>
	0.00%	40.99%	31.84%	45.62%	55.75%	61.49%	39.98%	38.44%
Unknown	0	0	0	0	0	6	6	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>0.00%</i>	<i>100.00%</i>	<i>100.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	1.72%	0.01%	0.00%
Total	0	24,491	14,232	4,373	3,738	348	47,182	43,096
	0.00%	51.91%	30.16%	9.27%	7.92%	0.74%	100.00%	91.34%
	<i>0.00%</i>	<i>51.91%</i>	<i>30.16%</i>	<i>9.27%</i>	<i>7.92%</i>	<i>0.74%</i>	<i>100.00%</i>	<i>91.34%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

25

Legend

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

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

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

Data Table Comments:

Sex/Gender:

More females (1,429,855 or 51.9%) than males (1,315,555 or 47.8%) are enrolled in aggregate foreign extramural research protocols.
More minority females (1,346,564 or 51.8%) than minority males (1,246,081 or 47.9%) are enrolled in aggregate foreign extramural research protocols.

Minority:

Approximately 94.4% (2,597,525) of participants in aggregate foreign extramural research (2,751,682) are classified as U.S. minorities.

Race:

Largest identified racial minority group is Asians at 87.7% following the 1997 OMB standards.
Largest identified racial minority group is Asian/Pacific Islanders at 51.9% following the 1977 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 0%.
According to the 1997 OMB standards, the smallest identified racial minority group is American Indian/Alaska Native at 0.04%.

Ethnicity:

1.78% 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 is White at 54.4%
Smallest identified racial group is Hawaiian/Pacific Islander at 0%.
Of the 48,106 participants, 75.7% are women and 23.8% are men.
9.3% of participants identified as Hispanic according to the 1977 OMB standards.

Table 18A. FOREIGN Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	186,858	128,365		68.70%
%	62.04%	71.69%		
Males	111,110	49,939		44.95%
%	36.89%	27.89%		
Unknown	3,244	743		22.90%
%	1.08%	0.41%		
TOTAL	301,212	179,047	59.44%	
Total %	100%	100.00%		

Total Number of
Protocols with Enrollment
Data:

71

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 46			
	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	9,233	2,660	7	45,729	1,387	3,050	62,066	56,240	3,277	2,549	62,066
	0.00%	7.43%	2.14%	0.01%	36.81%	1.12%	2.46%	49.96%	45.27%	2.64%	2.05%	49.96%
	0.00%	14.88%	4.29%	0.01%	73.68%	2.23%	4.91%	100.00%	90.61%	5.28%	4.11%	100.00%
	0.00%	48.94%	51.67%	87.50%	48.99%	51.87%	73.11%	49.96%	49.35%	69.80%	45.80%	49.96%
Male	8	9,633	2,488	1	47,618	1,287	999	62,034	57,722	1,418	2,894	62,034
	0.01%	7.75%	2.00%	0.00%	38.33%	1.04%	0.80%	49.94%	46.47%	1.14%	2.33%	49.94%
	0.01%	15.53%	4.01%	0.00%	76.76%	2.07%	1.61%	100.00%	93.05%	2.29%	4.67%	100.00%
	100.00%	51.06%	48.33%	12.50%	51.01%	48.13%	23.95%	49.94%	50.65%	30.20%	51.99%	49.94%
Unknown	0	0	0	0	3	0	123	126	3	0	123	126
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.10%	0.10%	0.00%	0.00%	0.10%	0.10%
	0.00%	0.00%	0.00%	0.00%	2.38%	0.00%	97.62%	100.00%	2.38%	0.00%	97.62%	100.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	2.95%	0.10%	0.00%	0.00%	2.21%	0.10%
Total	8	18,866	5,148	8	93,350	2,674	4,172	124,226	113,965	4,695	5,566	124,226
	0.01%	15.19%	4.14%	0.01%	75.15%	2.15%	3.36%	100.00%	91.74%	3.78%	4.48%	100.00%
	0.01%	15.19%	4.14%	0.01%	75.15%	2.15%	3.36%	100.00%	91.74%	3.78%	4.48%	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	1,285	1,992	3,277	15,279
	0.00%	0.00%	0.00%	0.00%	0.00%	27.37%	42.43%	69.80%	12.30%
	0.00%	0.00%	0.00%	0.00%	0.00%	39.21%	60.79%	100.00%	24.62%
	0.00%	0.00%	0.00%	0.00%	0.00%	51.28%	91.00%	69.80%	52.88%
Male	0	0	0	0	0	1,221	197	1,418	13,614
	0.00%	0.00%	0.00%	0.00%	0.00%	26.01%	4.20%	30.20%	10.96%
	0.00%	0.00%	0.00%	0.00%	0.00%	86.11%	13.89%	100.00%	21.95%
	0.00%	0.00%	0.00%	0.00%	0.00%	48.72%	9.00%	30.20%	47.12%
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%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	2,506	2,189	4,695	28,893
	0.00%	0.00%	0.00%	0.00%	0.00%	53.38%	46.62%	100.00%	23.26%
	0.00%	0.00%	0.00%	0.00%	0.00%	53.38%	46.62%	100.00%	23.26%
	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	100.00%	100.00%

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	108,311	2,858	1,917	7,315	4,391	124,792	113,086
	0.00%	61.20%	1.61%	1.08%	4.13%	2.48%	70.51%	63.90%
	<i>0.00%</i>	<i>86.79%</i>	<i>2.29%</i>	<i>1.54%</i>	<i>5.86%</i>	<i>3.52%</i>	<i>100.00%</i>	<i>90.62%</i>
	0.00%	76.82%	58.11%	45.13%	40.61%	49.80%	70.51%	75.31%
Male	0	32,640	2,060	1,625	8,324	4,427	49,076	36,325
	0.00%	18.44%	1.16%	0.92%	4.70%	2.50%	27.73%	20.52%
	<i>0.00%</i>	<i>66.51%</i>	<i>4.20%</i>	<i>3.31%</i>	<i>16.96%</i>	<i>9.02%</i>	<i>100.00%</i>	<i>74.02%</i>
	0.00%	23.15%	41.89%	38.25%	46.21%	50.20%	27.73%	24.19%
Unknown	0	37	0	706	2,375	0	3,118	743
	0.000%	0.02%	0.00%	0.40%	1.34%	0.00%	1.76%	0.42%
	<i>0.00%</i>	<i>1.19%</i>	<i>0.00%</i>	<i>22.64%</i>	<i>76.17%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>23.83%</i>
	0.00%	0.03%	0.00%	16.62%	13.18%	0.00%	1.76%	0.49%
Total	0	140,988	4,918	4,248	18,014	8,818	176,986	150,154
	0.00%	79.66%	2.78%	2.40%	10.18%	4.98%	100.00%	84.84%
	<i>0.00%</i>	<i>79.66%</i>	<i>2.78%</i>	<i>2.40%</i>	<i>10.18%</i>	<i>4.98%</i>	<i>100.00%</i>	<i>84.84%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

25

Legend

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

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

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

Data Table Comments:

Sex/Gender:

More females (186,858 or 62%) than males (111,110 or 37%) are enrolled in aggregate foreign intramural research protocols.

More minority females (128,365 or 71.7%) than minority males (49,939 or 27.9%) are enrolled in aggregate foreign intramural research protocols.

Minority:

Approximately 59.4% (179,047) of participants in aggregate foreign intramural research (301,212) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 75.1% following the 1997 OMB standards.

Largest identified racial minority group is Asian/Pacific Islander at 79.6% following the 1977 OMB standards.

Largest identified racial minority group is Asian at 15.2% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0%.

According to the 1997 OMB standards, the smallest identified racial minority groups are Hawaiian/Pacific Islander and American Indian/Alaska Native at 0.01%.

Ethnicity:

3.8% 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 is More Than One Race at 53.4%

Remaining participants identified the racial category of Unknown/Other at 46.6%

Of the 4,695 participants, 69.8% are women and 30.2% are men.

10.2% of participants identified as Hispanic according to the 1977 OMB standards.

Table 19A. FOREIGN Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	23,108	15,329		66.34%
%	54.79%	47.99%		
Males	16,523	14,075		85.18%
%	39.17%	44.06%		
Unknown	2,547	2,539		99.69%
%	6.04%	7.95%		
TOTAL	42,178	31,943	75.73%	
Total %	100%	100.00%		

Total Number of Protocols with Enrollment Data: 27

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	381	2,767	11,016	0	6,657	0	401	21,222	20,570	613	39	21,222
	0.98%	7.15%	28.45%	0.00%	17.19%	0.00%	1.04%	54.81%	53.13%	1.58%	0.10%	54.81%
	1.80%	13.04%	51.91%	0.00%	31.37%	0.00%	1.89%	100.00%	96.93%	2.89%	0.18%	100.00%
	97.94%	64.77%	42.60%	0.00%	87.87%	0.00%	64.26%	54.81%	54.08%	98.24%	61.90%	54.81%
Male	8	1,470	12,339	0	917	0	223	14,957	14,922	11	24	14,957
	0.02%	3.80%	31.87%	0.00%	2.37%	0.00%	0.58%	38.63%	38.54%	0.03%	0.06%	38.63%
	0.05%	9.83%	82.50%	0.00%	6.13%	0.00%	1.49%	100.00%	99.77%	0.07%	0.16%	100.00%
	2.06%	34.41%	47.72%	0.00%	12.10%	0.00%	35.74%	38.63%	39.23%	1.76%	38.10%	38.63%
Unknown	0	35	2,504	0	2	0	0	2,541	2,541	0	0	2,541
	0.00%	0.09%	6.47%	0.00%	0.01%	0.00%	0.00%	6.56%	6.56%	0.00%	0.00%	6.56%
	0.00%	1.38%	98.54%	0.00%	0.08%	0.00%	0.00%	100.00%	100.00%	0.00%	0.00%	100.00%
	0.00%	0.82%	9.68%	0.00%	0.03%	0.00%	0.00%	6.56%	6.68%	0.00%	0.00%	6.56%
Total	389	4,272	25,859	0	7,576	0	624	38,720	38,033	624	63	38,720
	1.00%	11.03%	66.78%	0.00%	19.57%	0.00%	1.61%	100.00%	98.23%	1.61%	0.16%	100.00%
	1.00%	11.03%	66.78%	0.00%	19.57%	0.00%	1.61%	100.00%	98.23%	1.61%	0.16%	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	380	0	0	0	1	0	232	613	14,397
	60.90%	0.00%	0.00%	0.00%	0.16%	0.00%	37.18%	98.24%	37.18%
	61.99%	0.00%	0.00%	0.00%	0.16%	0.00%	37.85%	100.00%	67.84%
	97.94%	0.00%	0.00%	0.00%	25.00%	0.00%	100.00%	98.24%	46.81%
Male	8	0	0	0	3	0	0	11	13,820
	1.28%	0.00%	0.00%	0.00%	0.48%	0.00%	0.00%	1.76%	35.69%
	72.73%	0.00%	0.00%	0.00%	27.27%	0.00%	0.00%	100.00%	92.40%
	2.06%	0.00%	0.00%	0.00%	75.00%	0.00%	0.00%	1.76%	44.93%
Unknown	0	0	0	0	0	0	0	0	2,539
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	6.56%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	99.92%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	8.26%
TOTAL	388	0	0	0	4	0	232	624	30,756
	62.18%	0.00%	0.00%	0.00%	0.64%	0.00%	37.18%	100.00%	79.43%
	62.18%	0.00%	0.00%	0.00%	0.64%	0.00%	37.18%	100.00%	79.43%
	100.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	100.00%	100.00%

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	3	0	929	951	3	1,886	932
	0.00%	0.09%	0.00%	26.87%	27.50%	0.09%	54.54%	26.95%
	0.00%	0.16%	0.00%	49.26%	50.42%	0.16%	100.00%	49.42%
	0.00%	100.00%	0.00%	78.53%	42.14%	21.43%	54.54%	78.52%
Male	0	0	1	254	1306	5	1,566	255
	0.00%	0.00%	0.03%	7.35%	37.77%	0.14%	45.29%	7.37%
	0.00%	0.00%	0.06%	16.22%	83.40%	0.32%	100.00%	16.28%
	0.00%	0.00%	100.00%	21.47%	57.86%	35.71%	45.29%	21.48%
Unknown	0	0	0	0	0	6	6	0
	0.000%	0.00%	0.00%	0.00%	0.00%	0.17%	0.17%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	42.86%	0.17%	0.00%
Total	0	3	1	1,183	2,257	14	3,458	1,187
	0.00%	0.09%	0.03%	34.21%	65.27%	0.40%	100.00%	34.33%
	0.00%	0.09%	0.03%	34.21%	65.27%	0.40%	100.00%	34.33%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

4

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:

Substantial numbers of women and minorities are enrolled in foreign extramural Phase III research protocols reported in FY2005. More females (23,108 or 54.8%) than males (16,523 or 39.17%) are enrolled in aggregate foreign extramural Phase III research protocols. More minority females (15,329 or 47.9%) than minority males (14,075 or 44.1%) are enrolled in aggregate foreign extramural Phase III research protocols.

Minority:

Approximately 76% (31,943) of participants in aggregate foreign extramural Phase III research (42,178) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 65.2% following the 1977 OMB standards.
Largest identified racial minority group is Hispanic at 34.2% following the 1977 OMB standards.
Largest identified racial minority group is Black at 66.8% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0%.

Ethnicity:

1.6% 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 is White at 37.8%
Smallest identified racial group is White at 0.6%
Of the 624 participants, 98.25% are women and 1.8% are men.
34.2% of participants identified as Hispanic according to the 1977 OMB standards.

III. Old Form: Total of All Subjects Reported Using the 1977 OMB Standards								
	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM
Female	0	3	0	929	951	3	1,886	932
	0.00%	0.09%	0.00%	26.87%	27.50%	0.09%	54.54%	26.95%
	<i>0.00%</i>	<i>0.16%</i>	<i>0.00%</i>	<i>49.26%</i>	<i>50.42%</i>	<i>0.16%</i>	<i>100.00%</i>	<i>49.42%</i>
	0.00%	100.00%	0.00%	78.53%	42.14%	21.43%	54.54%	78.52%
Male	0	0	1	254	1306	5	1,566	255
	0.00%	0.00%	0.03%	7.35%	37.77%	0.14%	45.29%	7.37%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.06%</i>	<i>16.22%</i>	<i>83.40%</i>	<i>0.32%</i>	<i>100.00%</i>	<i>16.28%</i>
	0.00%	0.00%	100.00%	21.47%	57.86%	35.71%	45.29%	21.48%
Unknown	0	0	0	0	0	6	6	0
	0.000%	0.00%	0.00%	0.00%	0.00%	0.17%	0.17%	0.00%
	<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>100.00%</i>	<i>0.00%</i>
	0.00%	0.00%	0.00%	0.00%	0.00%	42.86%	0.17%	0.00%
Total	0	3	1	1,183	2,257	14	3,458	1,187
	0.00%	0.09%	0.03%	34.21%	65.27%	0.40%	100.00%	34.33%
	<i>0.00%</i>	<i>0.09%</i>	<i>0.03%</i>	<i>34.21%</i>	<i>65.27%</i>	<i>0.40%</i>	<i>100.00%</i>	<i>34.33%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:

4

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:

Substantial numbers of women and minorities are enrolled in foreign extramural Phase III research protocols reported in FY2005. More females (23,108 or 54.8%) than males (16,523 or 39.17%) are enrolled in aggregate foreign extramural Phase III research protocols. More minority females (15,329 or 47.9%) than minority males (14,075 or 44.1%) are enrolled in aggregate foreign extramural Phase III research protocols.

Minority:

Approximately 76% (31,943) of participants in aggregate foreign extramural Phase III research (42,178) are classified as U.S. minorities.

Race:

Largest identified racial group is White at 65.2% following the 1977 OMB standards.
Largest identified racial minority group is Hispanic at 34.2% following the 1977 OMB standards.
Largest identified racial minority group is Black at 66.8% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaska native at 0%.
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific islander at 0%.

Ethnicity:

1.6% 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 is White at 37.8%
Smallest identified racial group is White at 0.6%
Of the 624 participants, 98.25% are women and 1.8% are men.
34.2% of participants identified as Hispanic according to the 1977 OMB standards.

Table 20A. FOREIGN Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2004 and Reported in FY2005: Percent Analysis

I. SUMMARY TOTALS: Old Form + New Form				
Sex /Gender	Total Enrollment	Minority Enrollment	Total % Minority	% Minority by Sex
Females	6,280	6,022		95.89%
%	48.61%	48.81%		
Males	6,640	6,316		95.12%
%	51.39%	51.19%		
Unknown	0	0		0%
%	0.00%	0.00%		
TOTAL	12,920	12,338	95.50%	
Total %	100%	100.00%		

Total Number of
Protocols with
Enrollment Data:

3

II. New Form (Part A): Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 2			
	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	52	0	0	0	258	310	52	0	258	310
	0.00%	0.00%	7.75%	0.00%	0.00%	0.00%	38.45%	46.20%	7.75%	0.00%	38.45%	46.20%
	0.00%	0.00%	16.77%	0.00%	0.00%	0.00%	83.23%	100.00%	16.77%	0.00%	83.23%	100.00%
	0.00%	0.00%	58.43%	0.00%	0.00%	0.00%	44.33%	46.20%	58.43%	0.00%	44.33%	46.20%
Male	0	0	37	0	0	0	324	361	37	0	324	361
	0.00%	0.00%	5.51%	0.00%	0.00%	0.00%	48.29%	53.80%	5.51%	0.00%	48.29%	53.80%
	0.00%	0.00%	10.25%	0.00%	0.00%	0.00%	89.75%	100.00%	10.25%	0.00%	89.75%	100.00%
	0.00%	0.00%	41.57%	0.00%	0.00%	0.00%	55.67%	53.80%	41.57%	0.00%	55.67%	53.80%
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	89	0	0	0	582	671	89	0	582	671
	0.00%	0.00%	13.26%	0.00%	0.00%	0.00%	86.74%	100.00%	13.26%	0.00%	86.74%	100.00%
	0.00%	0.00%	13.26%	0.00%	0.00%	0.00%	86.74%	100.00%	13.26%	0.00%	86.74%	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	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Male	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Unknown	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
TOTAL	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B
52
7.75%
16.77%
58.43%
37
5.51%
10.25%
41.57%
0
0.00%
0.00%
0.00%
89
13.26%
13.26%
100.00%

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	0	5,970	0	0	0	0	5,970	5,970
	0.00%	48.74%	0.00%	0.00%	0.00%	0.00%	48.74%	48.74%
	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>100.00%</i>
	0.00%	48.74%	0.00%	0.00%	0.00%	0.00%	48.74%	48.74%
Male	0	6,279	0	0	0	0	6,279	6,279
	0.00%	51.26%	0.00%	0.00%	0.00%	0.00%	51.26%	51.26%
	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>100.00%</i>
	0.00%	51.26%	0.00%	0.00%	0.00%	0.00%	51.26%	51.26%
Unknown	0	0	0	0	0	0	0	0
	0.000%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
	<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	0	12,249	0	0	0	0	12,249	12,249
	0.00%	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%	100.00%
	<i>0.00%</i>	<i>100.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>0.00%</i>	<i>100.00%</i>	<i>100.00%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols
with Enrollment Data:

1

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:

Substantial numbers of women and minorities are enrolled in intramural Phase III research protocols reported in FY2005.

More males (6,640 or 51.4%) than females (6,280 or 48.6%) are enrolled in aggregate foreign intramural Phase III research protocols.

More minority males (6,316 or 51.2%) than minority females (6,022 or 48.8%) are enrolled in aggregate foreign intramural Phase III research protocols.

Minority:

Approximately 95% (12,338) of participants in aggregate foreign intramural Phase III research (12,920) are classified as U.S. minorities.

Race:

Largest identified racial group is Unknown/Other at 86.7% following the 1997 OMB standards.

Largest identified racial minority group is Asian/Pacific Islander at 100% following the 1977 OMB standards (1 study).

Largest identified racial minority group is Black at 13.3% following the 1997 OMB standards.

Ethnicity:

0% of participants identified their ethnicity as Hispanic or Latino following the 1977 and 1997 OMB standards.