Department of Health and Human Services
National Institutes of Health

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

Comprehensive Report: Tracking of Clinical Research as Reported in Fiscal Year 2011 and Fiscal Year 2012

2013 Report

Table of Contents

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

HISTORICAL PERSPECTIVE

The establishment and implementation of policies for the inclusion of women and minorities in clinical research funded by the National Institutes of Health (NIH) originates from the women's health movement. Following the issuance of the report of the Public Health Service Task Force on Women's Health in 1985[1], the NIH established a policy in 1986 for the inclusion of women in clinical research. This policy, which ***urged*** the inclusion of women, was first published in the NIH Guide to Grants and Contracts in 1987[2]. Later that year, minority and other scientists at the NIH recognized the need to address the inclusion of minority populations. Therefore, in a later 1987 version of the NIH guide, a policy ***encouraging*** the inclusion of minorities in clinical studies was first published.

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

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

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

Strategies to ensure uniform implementation and adherence to the revised guidelines across the NIH included NIH –wide training of staff and Institutional Review Board chairs in 1994. An NIH Tracking and Inclusion Committee was established made up of representatives of the directors of each Institute and Center (ICs). This trans-NIH committee, convened by the Office of Research on Women's Health (ORWH) and co-chaired with a senior IC official, met regularly with a focus on consistent and widespread adherence to the NIH guidelines by all ICs[5]. Working in collaboration with the Office of

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[1] Report of the Public Health Task Force on Women's Health: US Public Health Service, 1985. Jan-Feb; 100(1):73-106.

[2] NIH Guide to Grants and Contracts, Vol. 16, No. 3, Pg. 2, January 23, 1987.

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

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

[5] The governance of inclusion policies and procedures has recently changed and is described further under the "Conclusion and Current Status" section of this report.

Extramural Research (OER), the Office of Intramural Research (OIR), and other NIH components, ORWH coordinated the development of data collection and reporting methodologies to ensure uniform standards and definitions in the reporting of data on women and minority participants in NIH-funded clinical research.

In addition, a variety of outreach activities were initiated to explain the revised policy to the scientific research community and to clear up common misunderstandings about the new requirements. Training was especially important in light of the 1990 General Accounting Office (GAO) findings that NIH's initial policy on inclusion was applied inconsistently, not well communicated, and often misunderstood within NIH and in the research community.

GAO Report, May 2000: Recommendations and Actions Taken

Following a Congressional request for an assessment of NIH progress in implementing the1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled *Women's Health - NIH Has Increased Its Efforts to Include Women in Research.*[6] It concluded that NIH had made significant progress in implementing a strengthened policy on including women in clinical research over the past decade.

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

- that the requirement be implemented so that Phase III clinical trials must be designed and carried out to allow for the valid analysis of differences between women and men, and this requirement be communicated to applicants as well as requiring peer review groups to determine whether each proposed Phase III clinical trial is required to have such a study design, and that summary statements document the decision of the initial reviewers; and

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

Immediately following the release of this report, 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 requirements for the inclusion of women and minority groups in NIH-funded clinical research where scientifically appropriate. In addition, NIH-defined Phase III clinical trials are required to include plans for analyzing, sex/gender, racial, and/or ethnic differences. Significant actions in 2001 included:

- Updating the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research[7] and posting it on the ORWH home page http://orwh.od.nih.gov/research/inclusion/index.asp and NIH web page, *Inclusion of Women and Minorities Policy Implementation* at: http://grants.nih.gov/grants/funding/women_min/women_min.htm

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

[7] NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, NIH Guide for Grants and Contracts, Amended 2001. Note: Current NIH policy guidelines are available in Appendix B of this report.

- Developing a new term and condition for awards made after October 1, 2000 that have NIH-defined Phase III clinical trials.

- Incorporating language in NIH solicitations for grant applications and contract proposals to clarify the submission requirement for NIH-defined Phase III clinical trials, a description of plans for sex/gender, racial, and/or ethnic analysis, including subgroups if applicable, and reporting enrollment annually and results of analyses as appropriate.

- Guidelines and instructions for reviewers and Scientific Review Officers (SROs) were developed to emphasize and clarify the need to review research projects that are classified as NIH-defined Phase III clinical trials for inclusion requirements and issues related to analyses by sex/gender, race, and/or ethnicity. Instructions were developed for properly documenting adherence to these policies in the summary statement.

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

Format Changes for Reporting Race and Ethnicity Data as of FY2002

Beginning in FY2002, NIH changed data reporting based on the 1997 Office of Management and Budget (OMB) revisions to the 1977 Directive 15 “Race and Ethnic Standards for Federal Statistics and Administrative Reporting,” which provides minimum standards for maintaining, collecting, and reporting data on race and ethnicity. In October 1997, OMB published “Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity.” 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, whereas the number of studies using the 1977 format (OLD FORM) has steadily decreased as the studies funded prior to FY2002 are completed.

The 1997 OMB reporting format (NEW FORM) and minimum standards do not allow for 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. Efforts to standardize definitions and business rules across NIH for data entered in the NIH electronic inclusion data system are reflected in data reported beginning in FY2002. Direct comparisons with data originating prior to FY 2002 data are difficult although trends can be approximated.

As demonstrated below, the primary differences between the 1977 (OLD FORM) and 1997 OMB (NEW FORM) minimum standards are: (1) the Hispanic population is considered an ethnic category and reported separately from racial data; (2) there are separate racial categories for Asian population data and Hawaiian and Pacific Islander population data; and 3) respondents are given the option of selecting more than one racial category and investigators aggregate and report these selections under the “More than one race” category on the form.

Racial and ethnic data from the OLD and NEW Forms are combined differently, as described below, for the purpose 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 in a single category.

- 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 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 Hispanics who identify as White and Hispanics who identify as Unknown/Not Reported race based on their ethnicity to the non-white racial categories.

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

Comparison of Old (1977) versus New (1997) Forms

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

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

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

Part A. Total Enrollment Report

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

Part B: Hispanic Enrollment Report

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

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

CONTINUING IMPLEMENTATION AND MONITORING ACTIVITIES

The Public Health Service 398 grant application for competing awards (PHS 398) has been significantly revised to provide additional instructions concerning the Women and Minorities Inclusion Policy. These PHS 398 instructions are also included in the federal application form SF-424 (R&R) for NIH grants using the federal Grants.gov system (http://grants.nih.gov/grants/ElectronicReceipt/index.htm) along with two significant changes in definitions. First, NIH requires use of a revised definition of clinical research that was reported in the 1997 Report of the NIH Director's Panel on Clinical Research and adopted by NIH. Second, NIH adopted the 1997 revisions to OMB Directive 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting" and requires use of the revised categories when reporting racial and ethnic data (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html). In addition, NIH policy reemphasized that NIH-defined Phase III clinical trials must be designed and conducted in a manner to allow for a valid analysis of whether the interventions being studied affect women or members of minority groups differently than other subjects.

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

Communication and Outreach Efforts to the Scientific Community

NIH staff members provide outreach to help increase the scientific community's understanding of NIH inclusion policies. These training and outreach efforts improve understanding of the inclusion policy and assist extramural and NIH intramural investigators to appropriately address these issues throughout the research funding 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/research/inclusion/outreach.asp) 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/research/inclusion/outreach.asp) have been published and distributed for investigators and NIH staff. These publications discuss the elements of recruitment and retention, the NIH inclusion policy, current OMB requirements for reporting race and ethnicity data, and information for application submission, peer review, and funding. Both the Outreach Notebook and the FAQs are posted on the ORWH website http://orwh.od.nih.gov/index.asp as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants.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.

Monitoring Compliance: Extramural and Intramural Population Data Analysis

Inclusion enrollment data from each NIH Institute and Center are presented in this report in summary figures and aggregate data tables[8]; providing documentation of inclusion monitoring with some degree of analysis of data. Caution should be used in interpreting these figures. Conclusions that can be reasonably drawn from the data are provided.

When assessing inclusion data, enrollment figures should not be directly compared to the national census figures. The goal of the NIH policy is to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will ultimately be generalizable to the entire population of the United States, and not to satisfy any proportional target based upon census data. The number of women, men, and/or representatives of racial/ethnic groups included in a particular study depends upon the scientific question addressed in the study and the prevalence among women, men and/or racial/ethnic groups of the disease, disorder, or condition under investigation.

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

NIH has monitored aggregate inclusion data for study populations since FY1994. Monitoring compliance with the NIH Inclusion policy is well established in all ICs. In May 2002, the NIH successfully deployed an electronic data system for monitoring inclusion data that was designed to provide easier entry of investigator-reported enrollment data and project monitoring for NIH staff.

Current Status

In the fall of 2009, the NIH Deputy Director requested that an internal task force be formed to advise the Director on the most effective ways for NIH to respond to PL 103-43 related to the inclusion of women and minorities as subjects in clinical research. The Task Force on Inclusion of Women, Minorities, and Other Populations in Clinical Research considered the strengths and weaknesses of the current NIH approach and potential alternative approaches for accomplishing the goals of NIH's current policy for including women and minorities in all NIH funded clinical research and specifically Phase III clinical trials.

A specific recommendation involved restructuring the governance of inclusion to more closely align it with the overall governance structure in place at the NIH. The Extramural Activities Working Group

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[8] The aggregate data tables are available in Appendix A.

(EAWG) Subcommittee on Inclusion Governance (E-SIG) was formed in November 2011. It is currently co-chaired by the Director of the NIH ORWH and the Director of the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD). Membership primarily includes senior level staff from the NIH Office of the Director and different Institutes and Centers (ICs) with participation of individuals from both extramural and intramural divisions.

The E-SIG has been meeting twice a month to discuss policy issues related to inclusion. In addition, OER has appointed a permanent NIH Inclusion Policy Officer to coordinate inclusion efforts across the NIH. The OER also received funds to re-engineer the data systems and workflow used to collect planned and actual enrollment data from investigators. It is anticipated that this new system will be released for use starting in 2014.

NIH staff continues to monitor, document, and work with grantees and contractors to ensure compliance with the inclusion policy. Program Officers/staff provide technical assistance to investigators as they develop their applications and proposals throughout the application process. Scientific Review Officers introduce and discuss with reviewers the guidelines and instructions for reviewing the inclusion of women and minorities in clinical research as well as the instructions and requirements for designing NIH-defined Phase III clinical trials in order that valid analyses can be conducted for sex/gender, racial, and/or ethnic 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 selected for payment are deficient in meeting policy requirements, grants management and program officials are required to withhold funding until the principal investigator has satisfactorily addressed the policy requirements.

Summary Report of NIH Inclusion Data: Comparison of FY2011 and FY2012 and Five and Ten Year Trend Data

INTRODUCTION

Data on inclusion are tabulated from human subject populations in NIH-defined clinical research[9] and NIH-defined Phase III clinical trials. Identification with specific sex/gender, racial, and ethnic categories is based on self-identification by the participants; participants always have the option to not identify. The NIH is mandated to monitor inclusion in all clinical research projects conducted or supported by the NIH; however, for the purpose of the summary report, the primary focus of the racial and ethnic analyses is on studies involving domestic populations. Appendix A contains all available data tables.

Because new clinical research studies begin each year while other studies may be ending, the inclusion data will vary from year to year due to the scientific topics under study and the prevalence of the diseases or conditions within each individual study.

Analysis of aggregate NIH inclusion data for FY2011 and FY2012 demonstrates that substantial numbers of women and men, and individuals of different races and ethnicities have been included as research subjects in NIH clinical research studies and NIH-defined Phase III clinical trials supported. In addition, five and ten year data have been provided to demonstrate trends in inclusion data over time. Caution should be utilized to avoid over-interpreting the figures and data tables that are provided.

The purpose of many of the summary figures in the body of the report is to demonstrate the relative distributions of participants on the basis of sex/gender, race, and/or ethnicity.

Some key trends:

- Total enrollment has ranged from approximately 14.8 million individuals in FY2003 to a high of over 23 million in FY2010. The most recent reported FY (FY2012) indicates participation of approximately 17.7 million individuals[10].
- Between FY2003 and FY2012, percent enrollment of females has ranged from a low of 56.1% in FY2010 to a high of 63.9% in FY2006. In FY2012, females comprised 57% of enrollment. These tables also include data on the participation of females excluding female-only studies[11].
- Total enrollment of minorities in clinical research has varied from a low of 28.6% in FY2008 to a high of 43.1%in FY2006. In FY2012, 36.5% of participants were from minority categories[12].
- Total enrollment of minorities in NIH-defined Phase III clinical trials has generally been on an increasing trend with a low of 24.7% in FY2003 to a high of 65.8% in FY2012[13]. These data are

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[9] NIH defines human clinical research as research with human subjects that is: (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 studies, or (d) development of new technologies. (2) Epidemiologic and Behavioral Studies. (3) Outcomes Research and Health Services Research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

[10] From Table 2A: Total Enrollment for All NIH Clinical Research from FY2003-FY2012 (10 Year Trend)

[11] From Table 2A: Total Enrollment for All NIH Clinical Research from FY2003-FY2012 (10 Year Trend)

[12] From Table 3A: Total Enrollment and Minority Enrollment for All NIH Clinical Research from FY2003-FY2012 (10 Year Trend). Note that these data also include foreign participants. Refer to additional tables in Section 3 of Appendix A for more summary data on percent of minorities enrolled in domestic research.

significantly impacted by the inclusion of foreign participants. In domestic NIH-defined Phase III trials, the five year trend (FY2008-FY2012) indicates a range of 20.2% in FY2008 to a high of 29% in FY2012[14].

Previous inclusion reports and aggregate enrollment figures for sex/gender, race, and ethnicity for FY1994 to the present can be found on the ORWH website at http://orwh.od.nih.gov/research/inclusion/index.asp.

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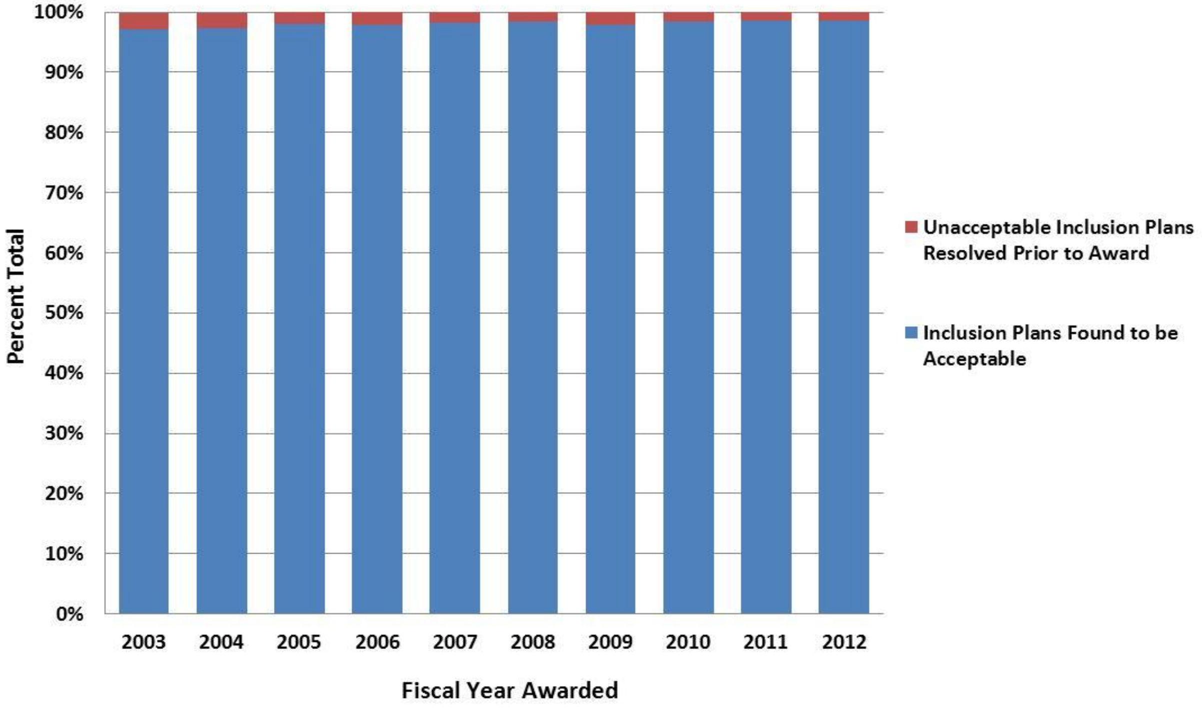
[13] From Table 4A: Total Enrollment and Minority Enrollment for All NIH-Defined Phase III Clinical Trials from FY2003-FY2012 (10 Year Trend)

[14] From Table 4B: Total Enrollment and Minority Enrollment for Domestic NIH-Defined Phase III Trials (Five Year Trend)

Acceptability of Inclusion Plans for Extramural Research Awards

Figure 1 depicts the percentage of competing clinical research awards in which the plans for the inclusion of women and minorities were found to be acceptable or unacceptable for fiscal years (FY) 2003 through 2012. The data indicate that the vast majority of applications have acceptable plans for the inclusion of women and minorities during the peer review process ranging from 97% acceptable/3% unacceptable starting in 2003 and improving to 99% acceptable/1% unacceptable for 2011 and 2012. This trend is quite stable.

Figure 1
Review of Inclusion Plans in Competing Clinical Research Awards



Metrics Based on Enrollment Records

Figure 2
NIH Clinical Research:
Number of Records with Enrollment

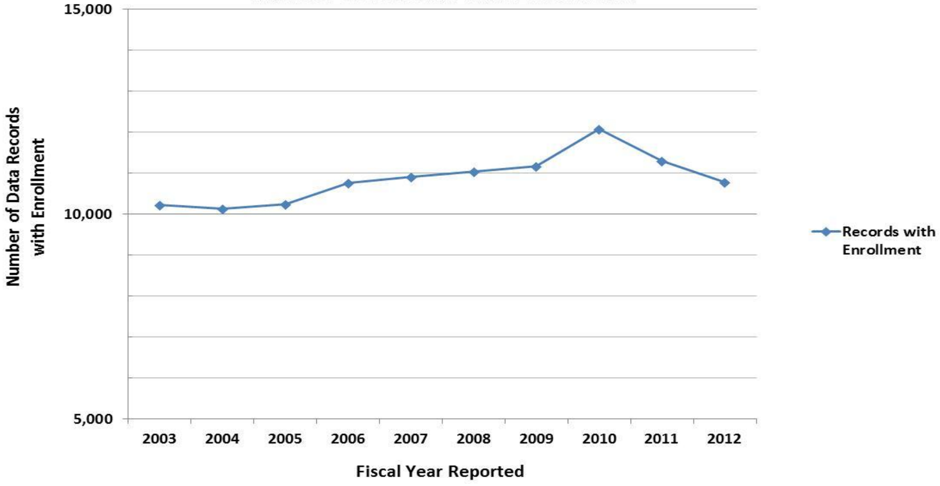


Figure 2 illustrates the trend data for the number of data records (also referred to as protocols) reporting enrollment each fiscal year since 2003. In 2003, there were 10,216 data records with enrollment. The highest number in the past ten years was 12,079 in FY2010. In FY2011 and FY2012, there are decreases in the number of data records with 11,296 and 10,774 respectively. Interpretation of these data should be approached with caution, because investigators and Institute/Center (IC) staff have some latitude in how inclusion data are reported and whether a given study will be divided into separate data records (often the case for multi-site studies or studies spanning multiple awards) or consolidate the data under a single record. In addition, these data only reflect those data records for which actual enrollment has been reported to the NIH; those where recruitment has not begun are not included. The decrease over the past two fiscal years may reflect the end of the ARRA (American Recovery and Reinvestment Act of 2009) funding period as well as a level NIH budget.

Figure 3 indicates the number of data records reporting enrollment for NIH-defined Phase III clinical trials. These data have ranged from a high of 852 in FY2003 to a low of 547 in FY2005. The data then increased starting in FY2006 and stabilized until declines for FY2011 (582) and FY2012 (548). These declines may be a result of a level NIH budget and/or the end of ARRA funding. Caution should be used in over-interpreting these data shifts given that PIs and the ICs have latitude in how to report inclusion data on data records.

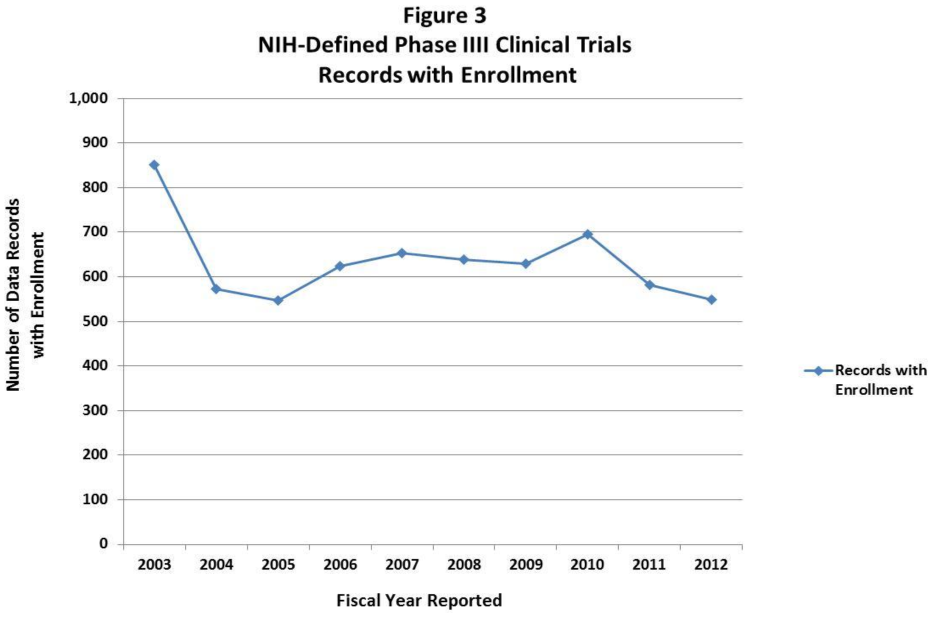


Figure 3
NIH-Defined Phase IIII Clinical Trials
Records with Enrollment

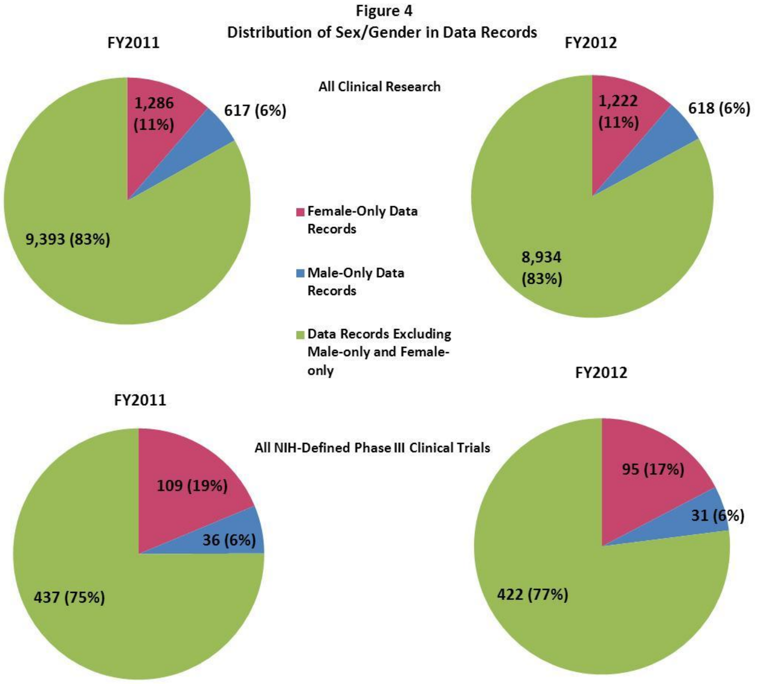


Figure 4
Distribution of Sex/Gender in Data Records

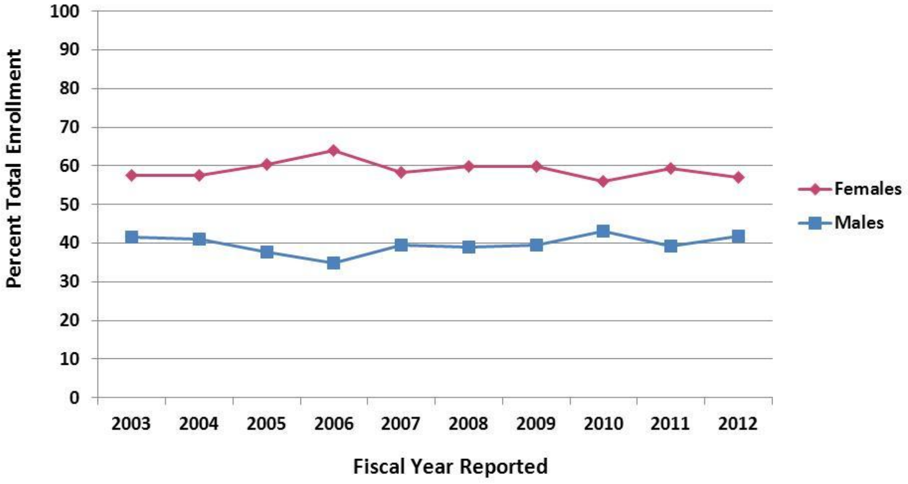
Figure 4 illustrates the distribution of sex/gender across data records for all NIH clinical research and NIH-defined Phase III clinical trials for FY2011 and FY2012. While the overall number of data records has decreased from FY2011 to FY2012 for both NIH clinical research and NIH-defined Phase III clinical trials, the percent distribution of male-only, female-only, and studies with males and females (excluding male-only and female-only) has remained quite stable. For NIH clinical research, there were no changes between FY2011 and FY2012 in percent distribution across data record groups with 11% for female-only data records, 6% for male-only data records, and 83% for data records excluding male-only and female-only studies. For NIH-defined Phase III clinical trials, there was a 2%

decrease in the proportion of female-only data records and a 2% increase in data records excluding male-only and female-only studies. The male-only data record distribution remained stable at 6%.

Metrics Based on Aggregate Enrollment: Sex/Gender:

Figure 5 illustrates the long term trend of recruitment by sex/gender in all NIH clinical research. In FY2003, there were 57.6% females and 41.4% males. This ten year trend has remained relatively stable with a return to 57% females and 41.8% males in FY2012. The ten year trend ranges from 56.1% females and 43.0% males (FY2010) to 63.9% females and 34.9% males (FY2006).[15]

Figure 5
Long-Term Trend of Enrollment by Sex/Gender in NIH Clinical Research



Figures 6 and 7 compare the percent enrollment by sex/gender for FY2011 and FY2012 for all NIH-defined clinical research. Figure 6 includes the percent enrollment totals for females, males, and unknowns; Figure 7 presents these data excluding female-only and male-only studies. In Figure 6, there appears to be a slight shift in the ratio of males to females enrolled in FY2012 as compared to FY2011 with a decrease in the proportion of females in FY2012 (from 60% to 57%) and a 3% increase in the proportion of males. This trend appears to mostly be the result of shifts in female-only or male-only studies. In Figure 7, there was only a 1% shift in the

Figure 6
Percent Enrollment by Sex/Gender in All NIH Clinical Research

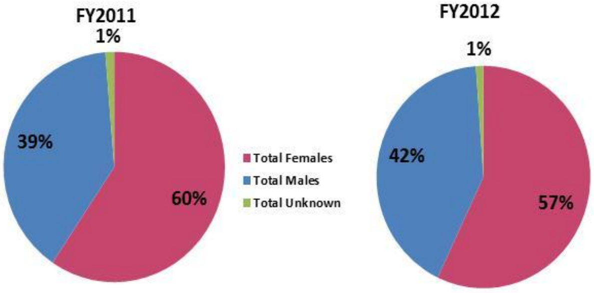
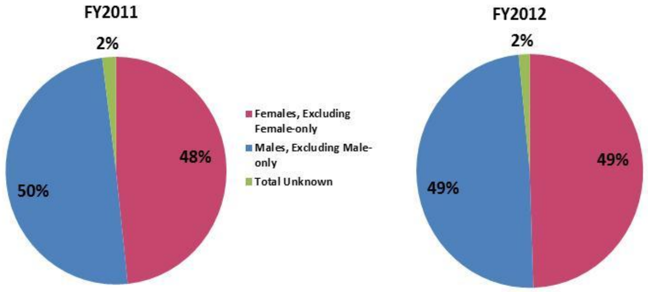


Figure 7
Percent Enrollment by Sex/Gender in All NIH Clinical Research
Excluding Male and Female Only Studies



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[15] In Figure 5, the percentage of females and males does not total to 100% in each fiscal year because there is also a small percentage of individuals reported with unknown sex/gender in each fiscal year.

proportion of females relative to males when female-only and male-only studies are excluded from the analysis.

Figure 8
Long-Term Trend of Enrollment by Sex/Gender in NIH-Defined Phase III Clinical Trials

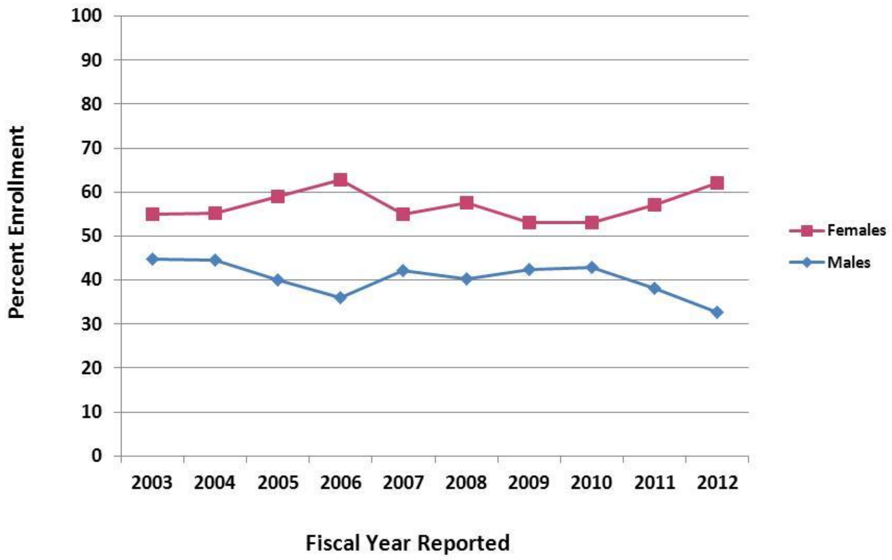


Figure 8 indicates the long term trend data of enrollment by sex/gender in NIH-defined Phase III clinical trials. There is an increase in the number of females (62.1%) in FY2012 over FY2011 (57%). The ten year trend ranges from 53% females and 42.3% males (FY2009) to 62.9% females and 36% males (FY2006)[16]. It is not entirely clear what is contributing to the differences in the distribution of females relative to males. It is possible that there have been changes in single sex/gender studies (beginning or ending) as well as shifts in the rate of participation of a given sex/gender in studies recruiting males and females.

In Figures 9 and 10, the distribution of enrollment by sex/gender in NIH-defined Phase III clinical trials is compared for FY2011 and FY2012. For all NIH-Defined Phase III clinical trials as well as those excluding male-only or female-only studies, there appears to be a modest increase in the number of females relative to males in these studies. This shift suggests that, at least for FY2011 and FY2012, the changes in proportion are due to changes in enrollment of trials including females and males rather than trials enrolling only females or only males.

Figure 9
Percent Enrollment by Sex/Gender in NIH-Defined Phase III Clinical Trials

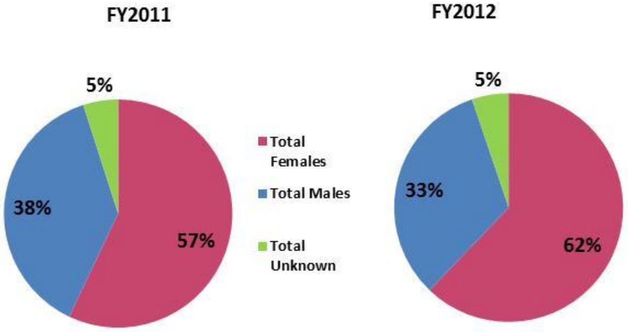
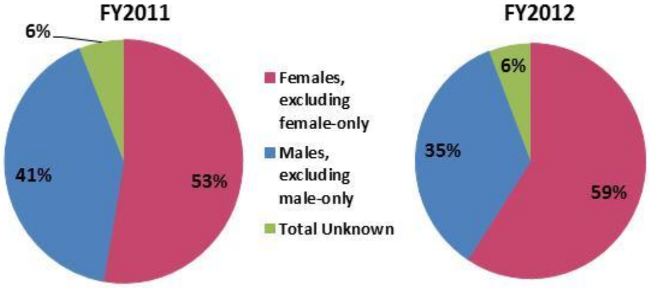


Figure 10
Percent Enrollment by Sex/Gender in NIH-Defined Phase III Clinical Trials excluding Male and Female Only Studies



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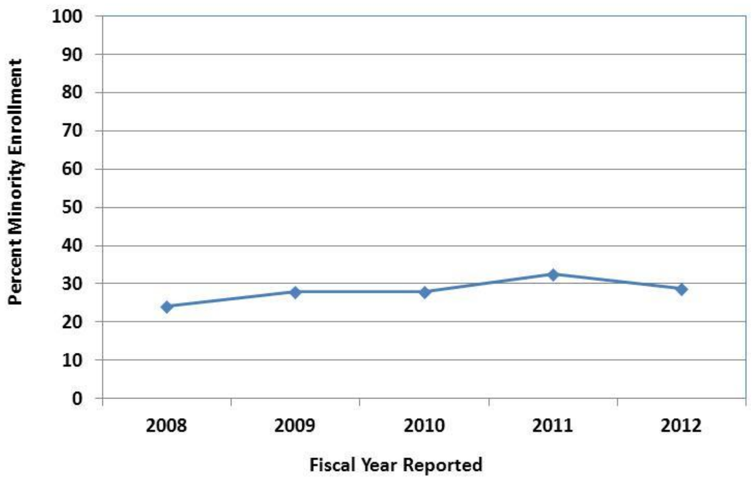
[16] In Figure 8, the percentage of females and males does not total to 100% in each fiscal year because there is also a small percentage of individuals reported with unknown sex/gender in each fiscal year.

Metrics Based on Aggregate Enrollment: Race and Ethnicity

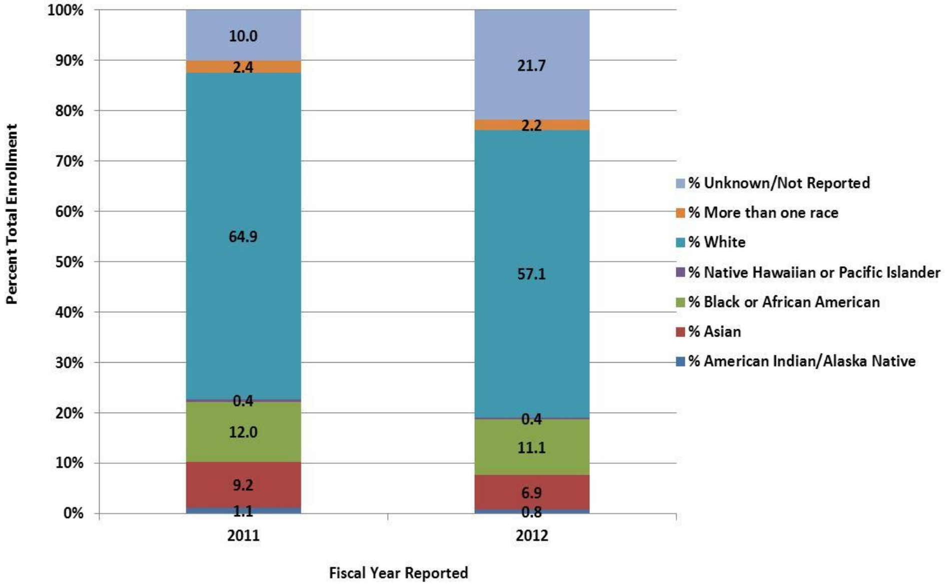
Figure 11 illustrates the percent of minority enrollment over the past five years in domestic clinical research. From FY2008-FY2011, there was a trend of increased enrollment which slightly decreased for FY2012. Specifically, there was 24.1% in FY2008, 27.8% in FY2009, 28.1% in FY2010, 32.6% in FY2011, and 28.7% in FY2012.

Figure 11
Minority Enrollment in NIH Domestic Clinical Research



The percent total enrollment for racial categories in domestic clinical research is presented for FY2011 and FY2012 in Figure 12. The proportions of most racial categories decreased or remained stable in FY2012 including American Indian/Alaska Native (-0.3%), Asian (-2.3%), Black or African American (-0.9%), Native Hawaiian or Pacific Islander (0.0%), White (-7.8%), and More than one race (-0.2%). There is an increase from 10.0% to 21.7% (+11.7%) in proportion of individuals in the Unknown/Not Reported category. These data are likely affected by a large study in the

Figure 12
Total Domestic Enrollment in NIH Clinical Research: Racial Categories



intramural division of the National Cancer Institute where sex/gender data were available from the health records dataset used; however, race and ethnicity information were not available to the investigator.

In Figure 13, the percent total enrollment for ethnic categories in domestic clinical research is illustrated for FY2011 and FY2012. The proportion of Not Hispanic participants decreased from 80% to 67.1% (-12.9%) with a smaller decrease in the proportion of Hispanic or Latino participants (-0.2%). The same trend observed in Figure 12 of an increase in the percentage of Unknown/Not Reported individuals is also observed in Figure 13(+13.1%) and is likely a result of the same intramural study where race and ethnicity of the dataset were unknown to the investigator.

Figure 13
Total Domestic Enrollment in NIH Clinical Research: Ethnic Categories

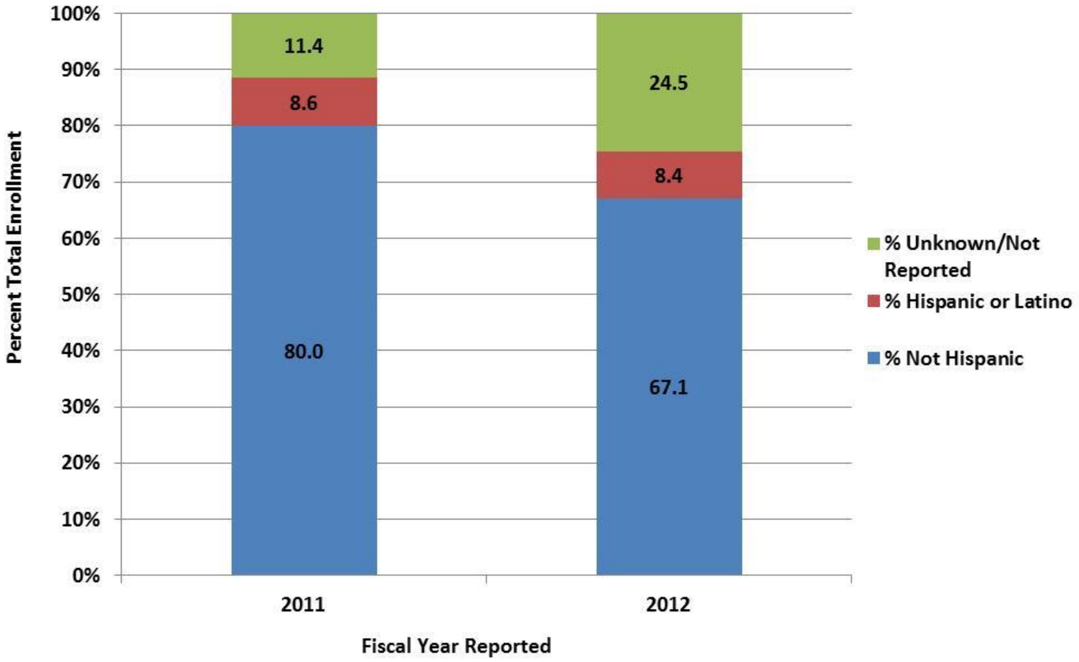


Figure 14
Minority Enrollment in NIH Domestic Phase III Clinical Trials

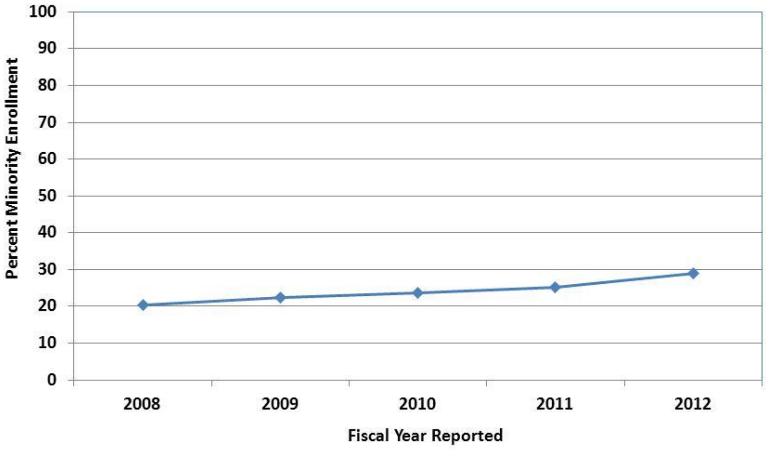


Figure 14 illustrates percent minority enrollment in domestic NIH-defined Phase III clinical trials. The overall trend in Phase III trials has been for modest increases in the proportion of minority populations enrolled over the past five years. Specifically, enrollment in FY2008 was 20.2% minority and has increased to 29.0% for FY2012.

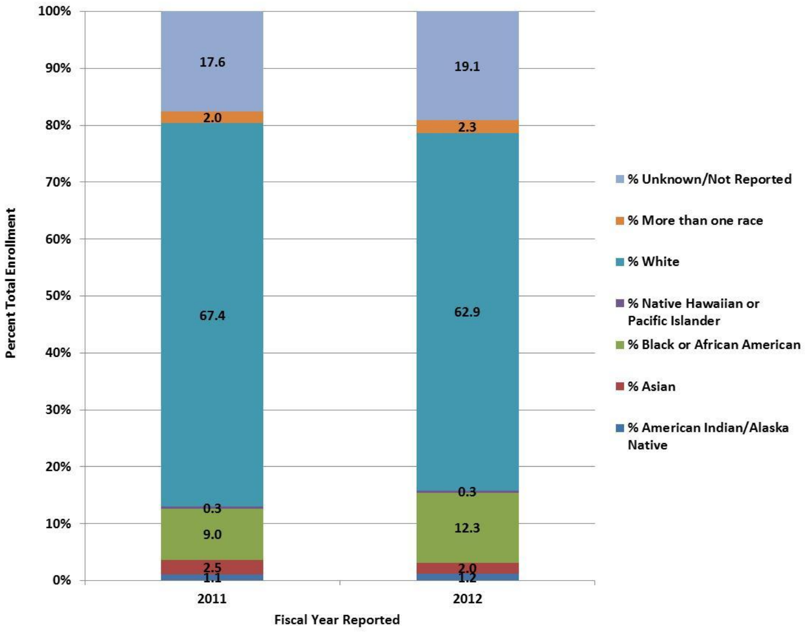


Figure 15
Total Domestic Enrollment in NIH-Defined Phase III Clinical Trials: Racial Categories

Figure 15 provides the percent total enrollment for racial categories in domestic NIH-defined Phase III clinical trials. Increases from FY2011 to FY2012 are noted in the following racial categories: American Indian/Alaska Native (+0.1%), Black or African American (+3.3%), More than one race (+0.3%), and Unknown/Not Reported (+1.5%). Decreases from FY2011 to FY2012 are noted for the Asian (-0.5%) and White (-4.5%) categories; Native Hawaiian or Pacific Islander remained stable at 0.3% of the distribution.

In Figure 16, the percent total enrollment for ethnic categories in domestic NIH-defined Phase III clinical trials indicates increases from FY2011 to FY2012 in the proportion of Hispanic or Latino (+0.9%) and Unknown/Not Reported (+2.3%) participants while the proportion of individuals in the Not Hispanic or Latino category decreased (-3.2%).

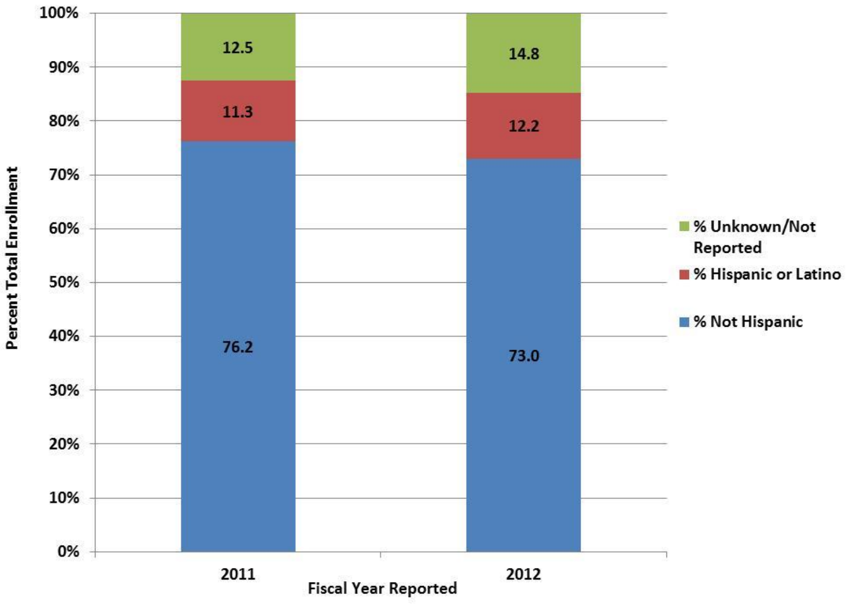


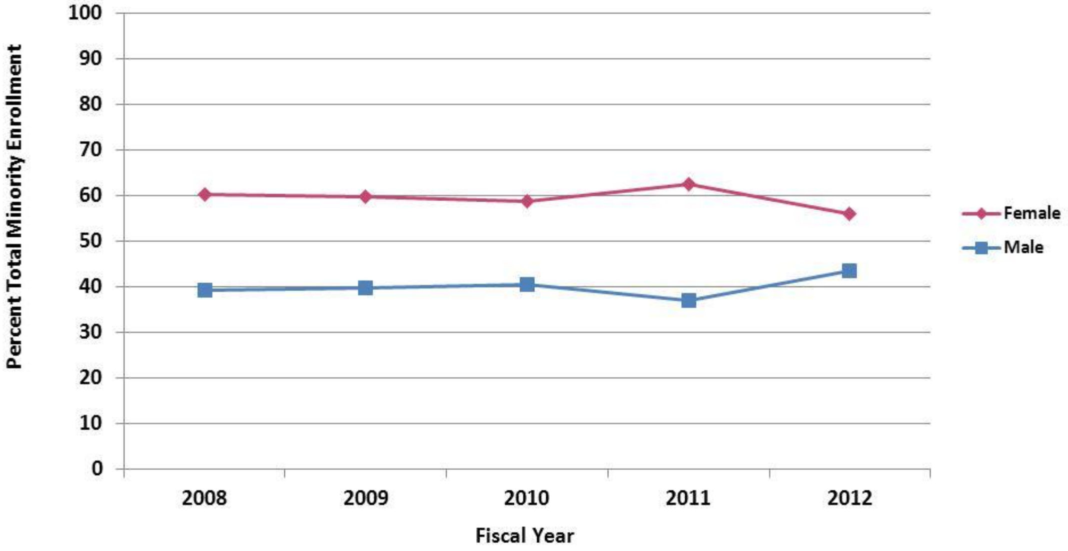
Figure 16
Total Domestic Enrollment in NIH-Defined Phase III Clinical Trials: Ethnic Categories

Metrics Based on Aggregate Enrollment: Domestic Race and Ethnicity by Sex/Gender

Figure 17 indicates the five year trend for percent minority enrollment broken out by sex/gender in domestic clinical research. The trend remained relatively stable through FY2008 (60.2% females, 39.4% males), FY2009 (59.9% females, 39.8% males), and FY2010 (58.9% females, 40.5% males). There is an increase in the proportion of female enrollment relative to male enrollment in FY2011 (62.5% females, 37.0% males) and a slight decrease in the percent female enrollment relative to male enrollment in FY2012 (55.9% females, 43.4% males)[17]. The decrease in the percent of male participants in FY2011 is likely influenced by conclusion of a large clinical study funded by the National Institute of Mental Health on suicide prevention in military personnel where the population consisted of more men than women. It is not clear what is contributing to the proportional shift back to closer relative distributions of males and females in FY2012 but could be the typical fluctuations observed due to changes in funding that occur each year. The overall trend suggests fairly stable distributions.

Figure 17

Minority Enrollment by Sex/Gender for Domestic NIH Clinical Research



In Figures 18 and 19, percent total enrollment figures are provided for each racial (Figure 18) and ethnic (Figure 19) category within the sex/gender categories of female, male, and unknown/not reported for domestic clinical research. When comparing the percent distribution of females across racial categories (Figure 18) for FY2011 and FY2012, there was a decrease in proportion of participants identifying as American Indian/Alaska Native (-0.4%), Asian (-3.5%), Black or African American (-0.6%), White (-11.3%), and More than one race (-0.2%). Increased proportions were observed for female participants identifying as Native Hawaiian or Pacific Islander (+0.1%) and females in the Unknown/Not Reported racial category (+16.0%).

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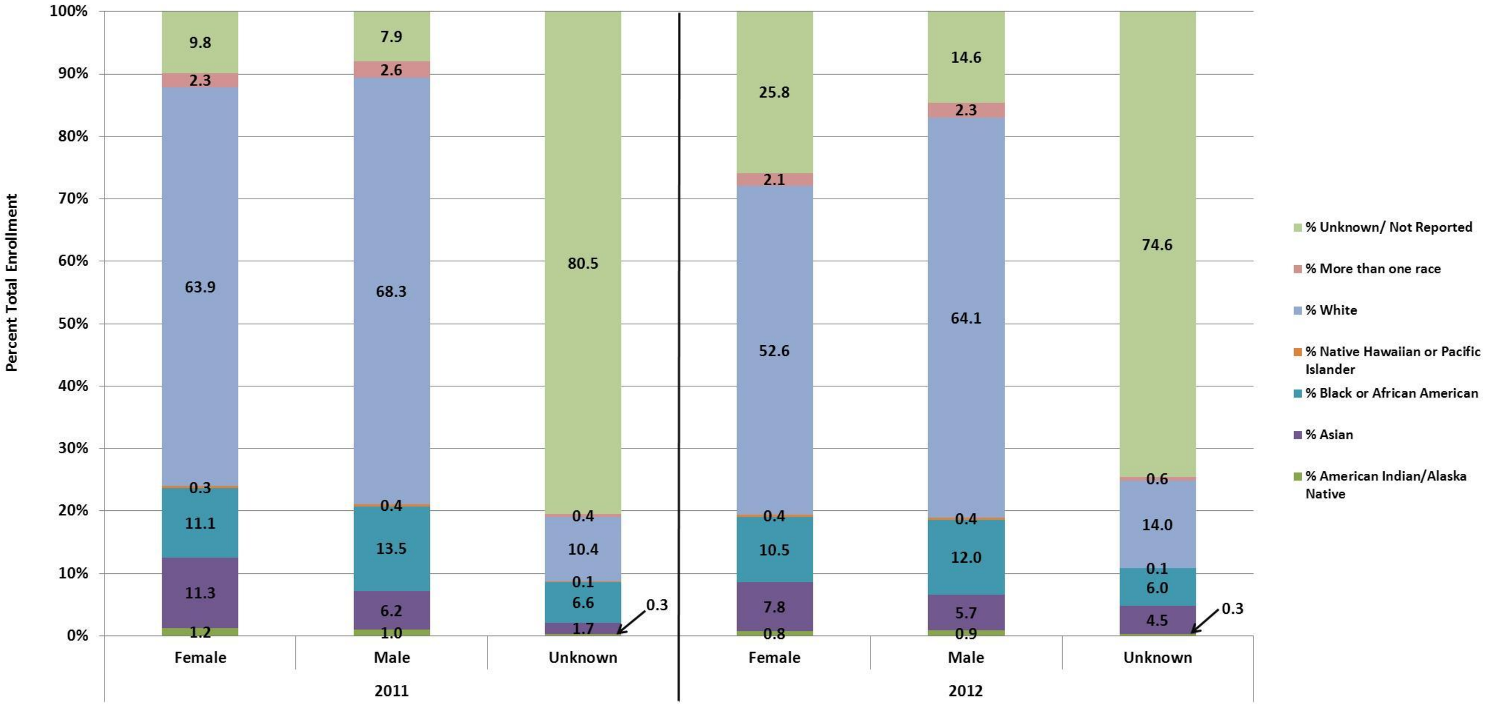
[17] In Figure 17, the percentage of females and males does not total to 100% in each fiscal year because there is also a small percentage of individuals reported with unknown sex/gender in each fiscal year.

When comparing the percent distribution of males across racial categories (Figure 18) for FY2011 and FY2012, there was a decrease in the proportion of males identifying as American Indian/Alaska Native (-0.1%), Asian (-0.5%), Black or African American (-1.5%), White (-4.2%), and More than one race (-0.3%). There was no change in the percent enrollment of Native Hawaiian or Pacific Islander males, and there was an increase in the proportion of males with Unknown/Not Reported race (+6.7%).

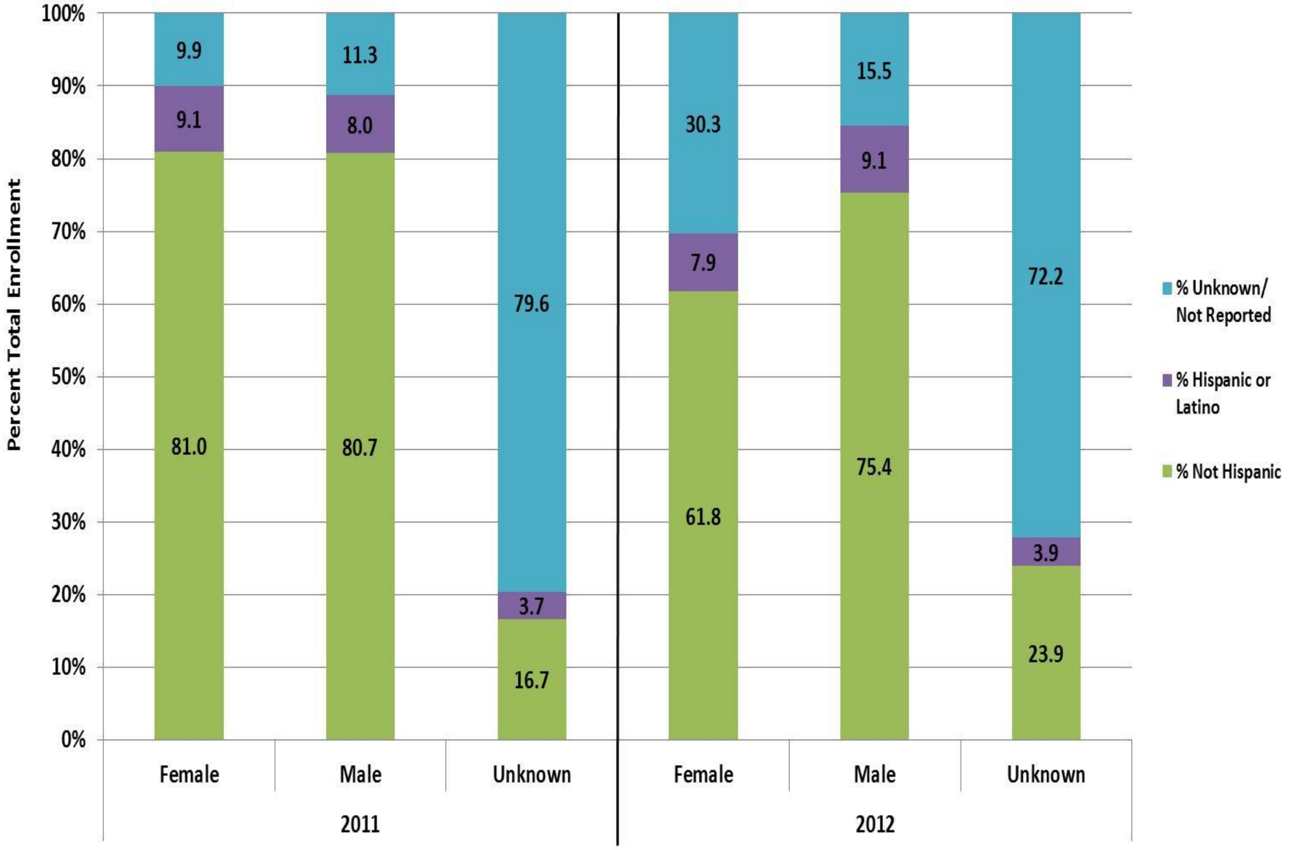
Figure 18
Enrollment for Domestic NIH Clinical Research: Sex/Gender by Race



When comparing individuals of unknown or not reported sex/gender, there were increased proportions of Asians (+2.8%), White (+3.6%), and More than one race (+0.2%). No changes in the percent enrollment were observed for individuals identifying as American Indian/Alaska Native and Native Hawaiian or Pacific Islander. Decreases in the percent enrollment were noted for Black or African American (-0.6%) and individuals of Unknown/Not Reported race (-5.9%).

Figure 19 illustrates the percent enrollment of ethnicity by sex/gender for FY2011 and FY2012. When comparing the percent enrollment of females by ethnicity in domestic clinical research for FY2011 and FY2012, Not Hispanic or Latino and Hispanic or Latino categories decreased (-19.2% and -1.2% respectively) while the proportion of females of Unknown/Not Reported ethnicity increased substantially (+20.4%). However, for males, increased percent enrollment was observed for Hispanic or Latino males (+1.1%) and males of Unknown/Not Report ethnicity (+4.2%) in FY2012 compared to FY2011. Males of Not Hispanic or Latino ethnicity decreased somewhat (-5.3%) from FY2011 to FY2012. These data may be affected by a large study in the intramural division of the National Cancer Institute where sex/gender data were available from the health records dataset used; however, race and ethnicity information were not available to the investigator.

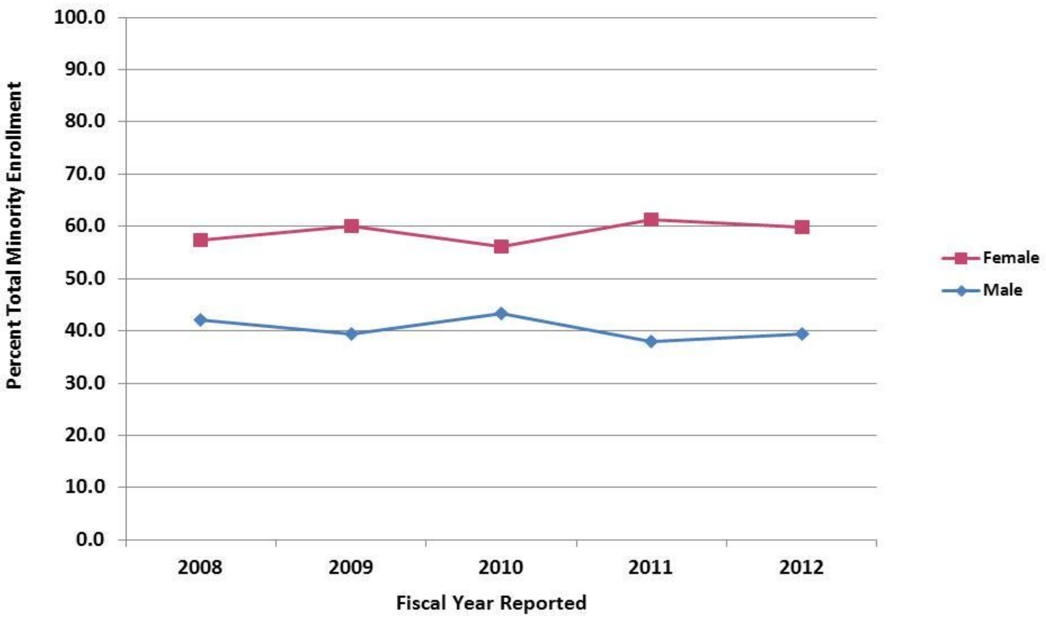
Figure 19
Enrollment for Domestic NIH Clinical Research: Sex/Gender by Ethnicity



When comparing individuals of unknown or not reported sex/gender, there were increased proportions of individuals identifying as Not Hispanic or Latino (+7.2%) and individuals identifying as Hispanic or Latino (+0.2%). A decrease in the percent enrollment was noted for individuals of Unknown/Not Reported sex/gender and ethnicity (-7.4%).

Figure 20 indicates the five year trend for percent minority enrollment broken out by sex/gender in domestic NIH-defined Phase III clinical trials. The trend has remained relatively stable with a range of 56.2% females to 43.3% males (FY2010) to 61.4% females to 38.0% males (FY2011), with a slight decrease in female enrollment relative to male enrollment in FY2012 (59.9% females, 39.4% males)[18].

Figure 20
Minority Enrollment by Sex/Gender for Domestic NIH-Defined Phase III Clinical Trials



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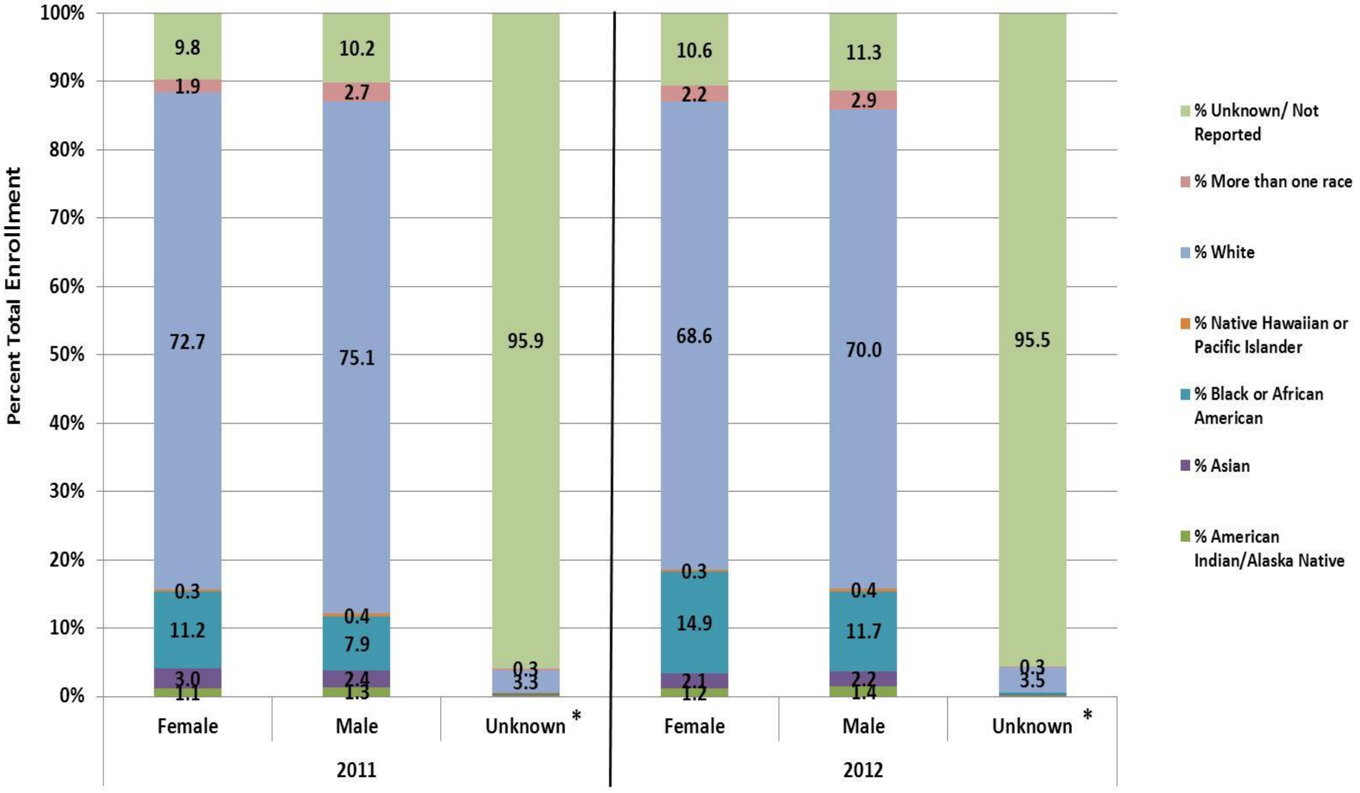
[18] In Figure 20, the percentage of females and males does not total to 100% in each fiscal year because there is also a small percentage of individuals reported with unknown sex/gender in each fiscal year.

In Figures 21 and 22, percent enrollment figures are provided for each racial (Figure 21) and ethnic (Figure 22) category within the sex/gender categories of female, male, and unknown for domestic NIH-defined Phase III clinical trials. When comparing the proportion of females for each racial category (Figure 21) between FY2011 and FY2012, decreases were observed for Asian (-0.9%) and White (-4.1%) racial categories, with increased percent enrollment for American Indian/Alaska Native (+0.1%), Black or African American (+3.7%), More than one race (+0.3%), and Unknown/Not Reported race (+0.8%). No change in percent distribution was observed for Native Hawaiian or Pacific Islander.

When comparing FY2011 and FY2012 percent enrollment of males across racial categories for domestic NIH-defined Phase III clinical trials, the same pattern is observed with decreased proportions in the racial categories of Asian (-0.2%) and White (-5.1%), with increases in American Indian/Alaska Native (+0.1%), Black or African American (+3.8%), More than one race (+0.2%), and Unknown/Not Reported race (+1.1%). No change in percent distribution was observed for Native Hawaiian or Pacific Islander.

Figure 21

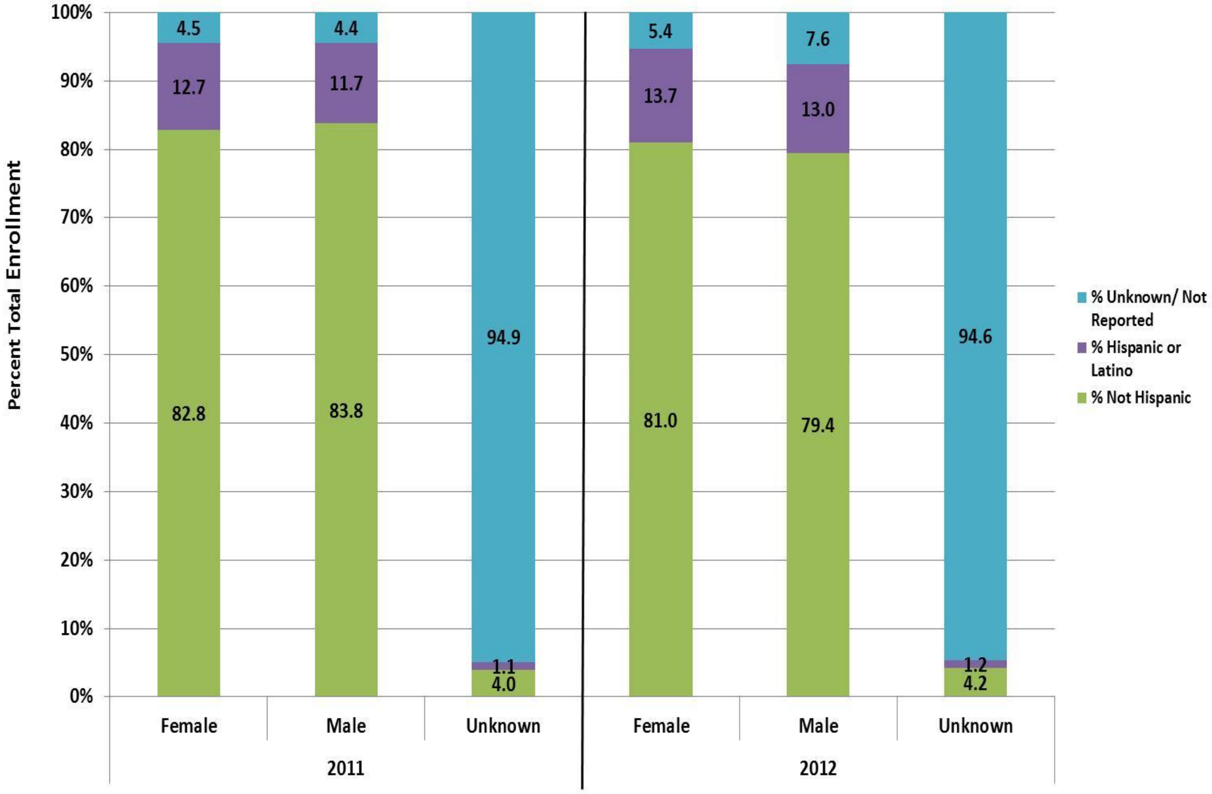
Enrollment for Domestic NIH-Defined Phase III Clinical Trials: Sex/Gender by Race



* Some categories too small to label

Figure 22 depicts the FY2011 and FY2012 percent enrollment for ethnicity broken out by sex/gender in domestic NIH-defined Phase III clinical trials. For females, a decrease in the proportion of Not Hispanic or Latino individuals is observed from FY2011 to FY2012 (-1.8%) while there is an increase in Hispanic or Latino (+1.0%) and Unknown/Not Reported (+0.9%) categories. The same pattern is observed for the percent enrollment of males for Not Hispanic or Latino (-4.4%), Hispanic or Latino (+1.3%), and Unknown/Not Reported ethnicity (+3.2%). For individuals of unknown sex/gender, there is a slight increase in the percent enrollment of Not Hispanic or Latino individuals (+0.2%) and Hispanic or Latino individuals (+0.1%) as well as a small decrease in those with Unknown/Not Reported ethnicity (-0.3%).

Figure 22
Enrollment for Domestic NIH-Defined Phase III Clinical Trials: Sex/Gender by Ethnicity



<u>Summary</u>

In summary, the overall trends demonstrate relatively stable inclusion of women and minorities in clinical research and NIH-defined Phase III clinical trials over time particularly with respect to the proportion of minority enrollment. Some variability in the distribution of males and females has been observed. Trend data will vary because the data for each year represent the net total of data resulting from: (1) studies continuing from the prior year; (2) the addition of new studies reported; and (3) the subtraction of studies that are no longer reported. When a large scale trial starts or ends, this can be illustrated by a shift in distributions of sex/gender and/or race and ethnicity. In addition, as noted in the report, an increase in racial and ethnic unknowns in the clinical research category was observed in FY2012 relative to FY2011 likely due to a large study in the intramural program using an existing dataset where sex/gender information was available to the investigator but racial and ethnic composition was not.

Appendix A

Aggregate Enrollment Data Tables: FY2011-FY2012 Data, Five Year (FY2008-FY2012) Trend Data, and Ten Year (FY2003-FY2012) Trend Data

Section 1: Metrics Based on Data Records

Table 1A: Total Number of Data Records for All NIH Clinical Research Reported from FY2003-FY2012

Fiscal Year (FY)	Total Number of Data Records	Data Records without Enrollment	Data Records with Enrollment	Domestic Data Records	Foreign Data Records	Data Records for Female-Only Studies	Data Records for Male-Only Studies	Data Records for Studies Excluding Male-only and Female-only studies*
FY2003	14,041	3,825	10,216	9,578	638	1,404	614	8,198
FY2004	14,512	4,387	10,125	9,760	365	1,470	511	8,144
FY2005	14,798	4,565	10,233	9,862	371	1,326	559	8,348
FY2006	15,320	4,562	10,758	10,294	464	1,338	581	8,839
FY2007	15,567	4,653	10,914	10,463	451	1,340	517	9,057
FY2008	15,598	4,553	11,045	10,548	497	1,272	529	9,244
FY2009	16,689	5,518	11,171	10,269	902	1,356	624	9,191
FY2010	17,251	5,172	12,079	11,189	890	1,373	691	10,015
FY2011	15,843	4,547	11,296	10,500	796	1,286	617	9,393
FY2012	15,541	4,767	10,774	9,982	792	1,222	618	8,934

* Data records excluding male-only and female-only include unknown gender, and combination of unknown and any gender(s).

Table 1B: Total Number of Data Records for All NIH-Defined Phase III Clinical Trials Reported from FY2003-FY2012

Fiscal Year (FY)	Total Number of Data Records	Data Records without Enrollment	Data Records with Enrollment	Domestic Data Records	Foreign Data Records	Data Records for Female-Only Studies	Data Records for Male-Only Studies	Data Records for Studies Excluding Male-only and Female-only studies*
FY2003	965	113	852	643	209	189	84	591
FY2004	689	116	573	549	24	147	34	395
FY2005	665	118	547	517	30	127	34	386
FY2006	760	136	624	564	60	118	47	459
FY2007	749	96	653	609	44	121	41	491
FY2008	726	87	639	585	54	126	42	471
FY2009	662	32	630	457	173	151	48	431
FY2010	743	47	696	540	156	140	61	495
FY2011	628	46	582	461	121	109	36	437
FY2012	565	17	548	441	107	95	31	422

* Data records excluding male-only and female-only include unknown gender, and combination of unknown and any gender(s).

Section 2: Metrics Based on Aggregate Enrollment by Sex/Gender

Table 2A: Total Enrollment for All NIH Clinical Research from FY2003-FY2012 (10 Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2003	14,772,254	8,514,481	57.6	6,121,496	41.4	136,277	0.9	3,044,558	20.6	351,987	2.4	5,469,923	37.0	5,769,509	39.1
FY2004	18,923,920	10,889,097	57.5	7,741,892	40.9	292,931	1.5	3,256,634	17.2	245,482	1.3	7,632,463	40.3	7,496,410	39.6
FY2005	15,722,752	9,503,922	60.4	5,941,907	37.8	276,923	1.8	3,469,692	22.1	317,697	2.0	6,034,230	38.4	5,624,210	35.8
FY2006	14,830,930	9,473,273	63.9	5,172,205	34.9	185,452	1.3	4,120,055	27.8	336,717	2.3	5,353,218	36.1	4,835,488	32.6
FY2007	17,448,458	10,152,589	58.2	6,887,791	39.5	408,078	2.3	9,000,648	51.6	377,803	2.2	1,151,941	6.6	6,509,988	37.3
FY2008	15,412,355	9,243,966	60.0	5,991,739	38.9	176,650	1.1	7,507,149	48.7	361,434	2.3	1,736,817	11.3	5,630,305	36.5
FY2009	19,138,738	11,439,143	59.8	7,570,646	39.6	128,949	0.7	4,830,093	25.2	396,076	2.1	6,609,050	34.5	7,174,570	37.5
FY2010	23,363,635	13,102,832	56.1	10,044,444	43.0	216,359	0.9	4,440,402	19.0	1,328,551	5.7	8,662,430	37.1	8,715,893	37.3
FY2011	15,992,456	9,499,682	59.4	6,287,306	39.3	205,468	1.3	4,562,652	28.5	1,210,876	7.6	4,937,030	30.9	5,076,430	31.7
FY2012	17,655,238	10,071,897	57.0	7,382,884	41.8	200,457	1.1	3,713,994	21.0	1,096,914	6.2	6,357,903	36.0	6,285,970	35.6

Table 2B: Total Enrollment for Domestic NIH Clinical Research from FY 2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2008	14,134,627	8,514,768	60.2	5,451,624	38.6	168,235	1.2	7,206,906	51.0	322,164	2.3	1,307,156	9.2	5,130,166	36.3
FY2009	17,962,879	10,748,744	59.8	7,093,702	39.5	120,433	0.7	4,619,125	25.7	347,894	1.9	6,129,619	34.1	6,745,808	37.6
FY2010	21,523,076	12,018,942	55.8	9,301,128	43.2	203,006	0.9	4,202,962	19.5	1,286,256	6.0	7,815,980	36.3	8,014,872	37.2
FY2011	13,470,269	7,974,958	59.2	5,314,952	39.5	180,359	1.3	4,318,845	32.1	1,172,588	8.7	3,656,113	27.1	4,142,364	30.8
FY2012	15,077,760	8,490,785	56.3	6,408,209	42.5	178,766	1.2	3,471,881	23.0	1,064,581	7.1	5,018,904	33.3	5,343,628	35.4

Table 2C: Total Enrollment for Domestic Extramural NIH Clinical Research from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2008	11,797,605	7,618,658	64.6	4,043,042	34.3	135,905	1.2	6,805,570	57.7	314,494	2.7	813,088	6.9	3,728,548	31.6
FY2009	15,546,350	9,842,191	63.3	5,624,890	36.2	79,269	0.5	4,460,062	28.7	338,422	2.2	5,382,129	34.6	5,286,468	34.0
FY2010	18,974,363	11,039,610	58.2	7,795,110	41.1	139,643	0.7	4,004,391	21.1	1,274,647	6.7	7,035,219	37.1	6,520,463	34.4
FY2011	10,853,602	6,961,241	64.1	3,779,319	34.8	113,042	1.0	4,108,737	37.9	1,162,408	10.7	2,852,504	26.3	2,616,911	24.1
FY2012	11,066,707	6,173,108	55.8	4,770,436	43.1	123,163	1.1	2,089,973	18.9	1,054,158	9.5	4,083,135	36.9	3,716,278	33.6

Table 2D: Total Enrollment for Domestic Intramural NIH Clinical Research from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2008	2,337,022	895,404	38.3	1,409,288	60.3	32,330	1.4	401,336	17.2	7,670	0.3	494,068	21.1	1,401,618	60.0
FY2009	2,416,529	906,553	37.5	1,468,812	60.8	41,164	1.7	159,063	6.6	9,472	0.4	747,490	30.9	1,459,340	60.4
FY2010	2,548,713	979,332	38.4	1,506,018	59.1	63,363	2.5	198,571	7.8	11,609	0.5	780,761	30.6	1,494,409	58.6
FY2011	2,616,667	1,013,717	38.7	1,535,633	58.7	67,317	2.6	210,108	8.0	10,180	0.4	803,609	30.7	1,525,453	58.3
FY2012	4,011,053	2,317,677	57.8	1,637,773	40.8	55,603	1.4	1,381,908	34.5	10,423	0.3	935,769	23.3	1,627,350	40.6

Table 2E: Total Enrollment for All NIH-Defined Phase III Clinical Trials from FY2003-FY2012 (10 Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2003	536,267	294,950	55.0	239,403	44.6	1,914	0.4	163,220	30.4	71,985	13.4	131,730	24.6	167,418	31.2
FY2004	545,367	301,353	55.3	242,913	44.5	1,101	0.2	160,148	29.4	72,762	13.3	141,205	25.9	170,151	31.2
FY2005	493,000	290,977	59.0	197,300	40.0	4,723	1.0	157,329	31.9	56,191	11.4	133,648	27.1	141,109	28.6
FY2006	499,430	314,066	62.9	179,975	36.0	5,389	1.1	167,624	33.6	27,723	5.6	146,442	29.3	152,252	30.5
FY2007	591,159	324,694	54.9	249,633	42.2	16,832	2.8	181,625	30.7	79,434	13.4	143,069	24.2	170,199	28.8
FY2008	792,578	455,612	57.5	319,732	40.3	17,234	2.2	219,673	27.7	79,613	10.0	235,939	29.8	240,119	30.3
FY2009	652,300	345,748	53.0	276,159	42.3	30,393	4.7	141,892	21.8	65,516	10.0	203,856	31.3	210,643	32.3
FY2010	769,885	408,181	53.0	330,808	43.0	30,896	4.0	119,103	15.5	62,315	8.1	289,078	37.5	268,493	34.9
FY2011	584,278	333,293	57.0	222,060	38.0	28,925	5.0	82,315	14.1	26,229	4.5	250,978	43.0	195,831	33.5
FY2012	603,136	374,819	62.1	197,019	32.7	31,298	5.2	58,916	9.8	10,288	1.7	315,903	52.4	186,731	31.0

Table 2F: Total Enrollment for Domestic NIH-Defined Phase III Clinical Trials from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2008	591,105	347,982	58.9	226,266	38.3	16,857	2.9	199,380	33.7	76,537	12.9	148,602	25.1	149,729	25.3
FY2009	590,886	347,533	58.8	226,715	38.4	16,638	2.8	123,192	20.8	59,643	10.1	224,341	38.0	167,072	28.3
FY2010	392,867	197,608	50.3	165,205	42.1	30,054	7.6	89,500	22.8	56,281	14.3	108,108	27.5	108,924	27.7
FY2011	303,916	160,644	52.9	116,345	38.3	26,927	8.9	64,095	21.1	24,337	8.0	96,549	31.8	92,008	30.3
FY2012	280,932	146,991	52.3	106,842	38.0	27,099	9.6	48,345	17.2	10,002	3.6	98,646	35.1	96,840	34.5

Table 2G: Total Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2008	585,023	345,372	59.0	223,021	38.1	16,630	2.8	199,371	34.1	76,378	13.1	146,001	25.0	146,643	25.1
FY2009	584,886	345,144	59.0	223,117	38.1	16,625	2.8	123,187	21.1	59,488	10.2	221,957	37.9	163,629	28.0
FY2010	382,998	190,415	49.7	162,542	42.4	30,041	7.8	84,405	22.0	56,117	14.7	106,010	27.7	106,425	27.8
FY2011	293,864	153,306	52.2	113,644	38.7	26,914	9.2	58,915	20.0	24,179	8.2	94,391	32.1	89,465	30.4
FY2012	270,082	138,811	51.4	104,185	38.6	27,086	10.0	42,375	15.7	9,837	3.6	96,436	35.7	94,348	34.9

Table 2H: Total Enrollment for Domestic Intramural NIH-Defined Phase III Clinical Trials from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Total Number of Females	Total % of Females	Total Number of Males	Total % of Males	Total Number of Unknown Sex/Gender	Total % of Unknown Sex/Gender	Number Enrolled in Female-only Studies	% Enrolled in Female-only Studies	Number Enrolled in Male-only Studies	% Enrolled in Male-only Studies	Number of Females, Excluding Female-only Studies	% of Females, Excluding Female-only Studies	Number of Males, Excluding Male-only Studies	% of Males, Excluding Male-only Studies
FY2008	6,082	2,610	42.9	3,245	53.4	227	3.7	9	0.1	159	2.6	2,601	42.8	3,086	50.7
FY2009	6,000	2,389	39.8	3,598	60.0	13	0.2	5	0.1	155	2.6	2,384	39.7	3,443	57.4
FY2010	9,869	7,193	72.9	2,663	27.0	13	0.1	5,095	51.6	164	1.7	2,098	21.3	2,499	25.3
FY2011	10,052	7,338	73.0	2,701	26.9	13	0.1	5,180	51.5	158	1.6	2,158	21.5	2,543	25.3
FY2012	10,850	8,180	75.4	2,657	24.5	13	0.1	5,970	55.0	165	1.5	2,210	20.4	2,492	23.0

Section 3: Metrics Based on Aggregate Enrollment of Race and Ethnicity: Clinical Research

Table 3A: Total Enrollment and Minority Enrollment for All NIH Clinical Research from FY2003-FY2012 (10 Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
FY2003	14,772,254	5,387,692	36.5
FY2004	18,923,920	7,611,611	40.2
FY2005	15,722,752	6,245,436	39.7
FY2006	14,830,930	6,388,316	43.1
FY2007	17,448,458	5,216,434	29.9
FY2008	15,412,355	4,412,106	28.6
FY2009	19,138,738	5,783,543	30.2
FY2010	23,363,635	7,510,763	32.1
FY2011	15,992,456	6,488,223	40.6
FY2012	17,655,238	6,446,175	36.5

Table 3B: Total Enrollment and Minority Enrollment for Domestic NIH Clinical Research (Old and New Forms) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
FY2008	14,134,627	3,521,691	24.1
FY2009	17,962,879	4,998,599	27.8
FY2010	21,523,076	6,041,531	28.1
FY2011	13,470,269	4,390,764	32.6
FY2012	15,077,760	4,332,559	28.7

Table 3C: Total Enrollment and Minority Enrollment for Domestic Extramural NIH Clinical Research (Old and New Forms) FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
FY2008	11,797,605	3,092,465	26.2
FY2009	15,546,350	4,419,314	28.4
FY2010	18,974,363	5,423,294	28.6
FY2011	10,853,602	3,746,667	34.5
FY2012	11,066,707	3,634,100	32.8

Table 3D: Total Enrollment and Minority Enrollment for Domestic Intramural NIH Clinical Research (Old and New Forms) FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
FY2008	2,337,022	459,360	19.7
FY2009	2,416,529	579,285	24.0
FY2010	2,548,713	618,237	24.3
FY2011	2,616,667	644,097	24.6
FY2012	4,011,053	698,459	17.4

Table 3E: Total Enrollment for All NIH Clinical Research Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/Other	% Unknown/Other
FY2008	626,419	146,171	23.3	1,930	0.3	16,258	2.6	99,164	15.8	28,819	4.6	460,533	73.5	19,715	3.1
FY2009	389,466	74,571	19.1	1,213	0.3	11,652	3.0	42,405	10.9	19,301	5.0	299,115	76.8	15,780	4.1
FY2010	266,757	57,755	21.7	682	0.3	9,081	3.4	32,551	12.2	15,441	5.8	203,303	76.2	5,699	2.1
FY2011	18,294	3,824	20.9	60	0.3	382	2.1	1,787	9.8	1,595	8.7	13,950	76.3	520	2.8
FY2012	7,163	3,250	45.4	55	0.8	281	3.9	1,478	20.6	1,436	20.0	3,636	50.8	277	3.9

Table 3F: Total Enrollment for All NIH Clinical Research Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	14,785,936	4,265,935	28.9	134,494	0.9	1,168,053	7.9	1,835,035	12.4	48,560	0.3	9,651,267	65.3
FY2009	18,749,272	5,708,972	30.4	154,515	0.8	1,840,539	9.8	2,287,577	12.2	50,339	0.3	12,790,945	68.2
FY2010	23,096,878	7,453,008	32.3	361,229	1.6	2,133,596	9.2	2,949,614	12.8	150,856	0.7	15,278,117	66.1
FY2011	15,974,162	6,484,399	40.6	360,626	2.3	2,351,721	14.7	2,112,553	13.2	47,794	0.3	9,154,454	57.3
FY2012	17,648,075	6,442,925	36.5	335,460	1.9	2,157,236	12.2	2,140,641	12.1	56,721	0.3	9,070,528	51.4

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	181,941	1.2	1,766,586	11.9
FY2009	323,839	1.7	1,301,518	6.9
FY2010	358,946	1.6	1,864,520	8.1
FY2011	349,281	2.2	1,597,733	10.0
FY2012	355,539	2.0	3,531,950	20.0

Table 3G: Total Enrollment for All NIH Clinical Research Ethnic Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	11,881,644	80.4	1,116,699	7.6	1,787,594	12.1
FY2009	16,033,547	85.5	1,302,944	6.9	1,412,781	7.5
FY2010	18,962,836	82.1	1,958,060	8.5	2,175,982	9.4
FY2011	12,687,228	79.4	1,641,383	10.3	1,645,551	10.3
FY2012	12,091,772	68.5	1,778,148	10.1	3,778,155	21.4

Table 3H: Total Enrollment for Domestic NIH Clinical Research Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic, not White	% Hispanic, not White	White	% White	Unknown/ Other	% Unknown/Other
FY2008	622,354	111,795	18.0	12,505	2.0	11,366	1.8	62,753	10.1	25,171	4.0	350,300	56.3	160,259	25.8
FY2009	372,018	72,601	19.5	1,165	0.3	11,204	3.0	42,213	11.3	18,019	4.8	284,717	76.5	14,700	4.0
FY2010	256,522	55,229	21.5	656	0.3	8,510	3.3	31,785	12.4	14,278	5.6	195,779	76.3	5,514	2.1
FY2011	17,878	3,723	20.8	60	0.3	380	2.1	1,730	9.7	1,553	8.7	13,663	76.4	492	2.8
FY2012	7,163	3,250	45.4	55	0.8	281	3.9	1,478	20.6	1,436	20.0	3,636	50.8	277	3.9

Table 3I: Total Enrollment for Domestic NIH Clinical Research Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	13,512,273	3,409,896	25.2	111,668	0.8	719,287	5.3	1,582,616	11.7	41,780	0.3	9,256,041	68.5
FY2009	17,590,861	4,925,998	28.0	145,541	0.8	1,396,409	7.9	2,066,817	11.7	47,981	0.3	12,387,427	70.4
FY2010	21,266,554	5,986,302	28.1	180,458	0.8	1,396,324	6.6	2,521,997	11.9	150,539	0.7	14,917,917	70.1
FY2011	13,452,391	4,387,041	32.6	153,066	1.1	1,234,591	9.2	1,610,345	12.0	47,247	0.4	8,731,310	64.9
FY2012	15,070,597	4,329,309	28.7	123,329	0.8	1,033,995	6.9	1,665,516	11.1	56,474	0.4	8,598,595	57.1

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	168,750	1.2	1,632,131	12.1
FY2009	302,563	1.7	1,244,123	7.1
FY2010	333,164	1.6	1,766,155	8.3
FY2011	325,613	2.4	1,350,219	10.0
FY2012	329,050	2.2	3,263,638	21.7

Table 3J: Total Enrollment for Domestic NIH Clinical Research Ethnic Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	10,871,618	80.5	945,603	7.0	1,695,053	12.5
FY2009	15,090,139	85.8	1,142,171	6.5	1,358,551	7.7
FY2010	17,523,002	82.4	1,650,926	7.8	2,092,626	9.8
FY2011	10,765,968	80.0	1,151,089	8.6	1,535,334	11.4
FY2012	10,115,385	67.1	1,263,122	8.4	3,692,090	24.5

Table 3K: Total Enrollment for Domestic Extramural NIH Clinical Research Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2008	424,022	70,168	16.5	1,610	0.4	9,483	2.2	39,092	9.2	19,983	4.7	337,016	79.5	16,838	4.0
FY2009	210,541	34,534	16.4	884	0.4	4,456	2.1	20,257	9.6	8,937	4.2	163,706	77.8	12,301	5.8
FY2010	92,838	16,843	18.1	348	0.4	1,554	1.7	9,305	10.0	5,636	6.1	73,120	78.8	2,875	3.1
FY2011	17,878	3,723	20.8	60	0.3	380	2.1	1,730	9.7	1,553	8.7	13,663	76.4	492	2.8
FY2012	7,163	3,250	45.4	55	0.8	281	3.9	1,478	20.6	1,436	20.0	3,636	50.8	277	3.9

Table 3L: Total Enrollment for Domestic Extramural NIH Clinical Research Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	11,373,583	3,022,297	26.6	91,219	0.8	682,794	6.0	1,342,138	11.8	37,213	0.3	7,673,578	67.5
FY2009	15,335,809	4,384,780	28.6	124,638	0.8	1,359,843	8.9	1,806,313	11.8	46,579	0.3	10,854,012	70.8
FY2010	18,881,525	5,406,451	28.6	157,306	0.8	1,357,807	7.2	2,241,304	11.9	146,735	0.8	13,331,570	70.6
FY2011	10,835,724	3,742,944	34.5	127,914	1.2	1,182,405	10.9	1,295,314	12.0	42,554	0.4	6,986,561	64.5
FY2012	11,059,544	3,630,850	32.8	96,939	0.9	969,446	8.8	1,340,160	12.1	50,939	0.5	6,736,548	60.9

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	158,379	1.4	1,388,262	12.2
FY2009	157,430	1.0	986,976	6.4
FY2010	180,093	1.0	1,466,710	7.8
FY2011	178,911	1.7	1,022,065	9.4
FY2012	181,044	1.6	1,684,468	15.2

Table 3M: Total Enrollment for Domestic Extramural NIH Clinical Research Ethnic Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	9,045,771	79.5	867,052	7.6	1,460,761	12.8
FY2009	13,306,619	86.8	1,061,093	6.9	968,097	6.3
FY2010	15,672,806	83.0	1,560,272	8.3	1,648,447	8.7
FY2011	8,715,026	80.4	1,044,252	9.6	1,076,446	9.9
FY2012	8,047,787	72.8	1,128,442	10.2	1,883,315	17.0

Table 3N: Total Enrollment for Domestic Intramural NIH Clinical Research Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)[19]

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2008	197,916	74,958	37.9	291	0.1	6,681	3.4	60,038	30.3	7,948	4.0	120,201	60.7	2,757	1.4
FY2009	161,477	38,067	23.6	281	0.2	6,748	4.2	21,956	13.6	9,082	5.6	121,011	74.9	2,399	1.5
FY2010	163,684	38,386	23.5	308	0.2	6,956	4.2	22,480	13.7	8,642	5.3	122,659	74.9	2,639	1.6
FY2011	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3O: Total Enrollment for Domestic Intramural NIH Clinical Research Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/Alaska Native	% American Indian/Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	2,139,106	384,402	18.0	21,335	1.0	36,225	1.7	237,793	11.1	4,556	0.2	1,575,167	73.6
FY2009	2,255,052	541,218	24.0	20,903	0.9	36,566	1.6	260,504	11.6	1,384	0.1	1,533,415	68.0
FY2010	2,385,029	579,851	24.3	23,152	1.0	38,517	1.6	280,693	11.8	3,804	0.2	1,586,347	66.5
FY2011	2,616,667	644,097	24.6	25,152	1.0	52,186	2.0	315,031	12.0	4,693	0.2	1,744,749	66.7
FY2012	4,011,053	698,459	17.4	26,390	0.7	64,549	1.6	325,356	8.1	5,535	0.1	1,862,047	46.4

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	10,157	0.5	253,873	11.9
FY2009	145,133	6.4	257,147	11.4
FY2010	153,071	6.4	299,445	12.6
FY2011	146,702	5.6	328,154	12.5
FY2012	148,006	3.7	1,579,170	39.4

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[19] Data have zeroes for FY2011 and FY2012 because the intramural programs have migrated all data to the new data form (1997 OMB definitions)

Table 3P: Total Enrollment for Domestic Intramural NIH Clinical Research Ethnic Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	1,817,816	85.0	77,927	3.6	243,363	11.4
FY2009	1,783,520	79.1	81,078	3.6	390,454	17.3
FY2010	1,850,196	77.6	90,654	3.8	444,179	18.6
FY2011	2,050,942	78.4	106,837	4.1	458,888	17.5
FY2012	2,067,598	51.5	134,680	3.4	1,808,790	45.1

Section 4: Metrics Based on Aggregate Enrollment of Race and Ethnicity: NIH-Defined Phase III Clinical Trials

Table 4A: Total Enrollment and Minority Enrollment for All NIH-Defined Phase III Clinical Trials from FY2003-FY2012 (10 Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
FY2003	536,267	132,302	24.7
FY2004	545,367	150,456	27.6
FY2005	493,000	154,191	31.3
FY2006	499,430	167,446	33.5
FY2007	591,159	244,932	41.4
FY2008	792,578	270,899	34.2
FY2009	652,300	291,949	44.8
FY2010	769,885	447,187	58.1
FY2011	584,278	347,770	59.5
FY2012	603,136	396,714	65.8

Table 4B: Total Enrollment and Minority Enrollment for Domestic NIH-Defined Phase III Clinical Trials (Old and New Forms) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
FY2008	591,105	119,582	20.2
FY2009	433,895	97,079	22.4
FY2010	392,867	92,509	23.5
FY2011	303,916	76,415	25.1
FY2012	280,932	81,420	29.0

Table 4C: Total Enrollment and Minority Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials (Old and New Forms) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
FY2008	585,023	117,869	20
FY2009	427,895	95,512	22
FY2010	382,998	89,006	23
FY2011	293,864	72,819	25
FY2012	270,082	77,371	29

Table 4D: Total Enrollment and Minority Enrollment for Domestic Intramural NIH-Defined Phase III Clinical Trials (Old and New Forms) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Number Enrolled	Number of Minorities Enrolled	% of Minorities Enrolled
2008	6,082	1,713	28.2
2009	6,000	1,567	26.1
2010	9,869	3,503	35.5
2011	10,052	3,596	35.8
2012	10,850	4,049	37.3

Table 4E: Total Enrollment for All NIH-Defined Phase III Clinical Trials Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Data Records	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown /Other	% Unknown /Other
FY2008	232,544	164	37,529	16.1	900	0.4	4,542	2.0	22,445	9.7	9,642	4.1	190,753	82.0	4,262	1.8
FY2009	165,737	196	25,344	15.3	613	0.4	3,291	2.0	14,956	9.0	6,484	3.9	136,082	82.1	4,311	2.6
FY2010	78,435	62	11,601	14.8	296	0.4	1,192	1.5	6,888	8.8	3,225	4.1	66,085	84.3	749	1.0
FY2011	1,159	3	13	1.1	1	0.1	3	0.3	9	0.8	0	0.0	1,088	93.9	58	5.0
FY2012	0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 4F: Total Enrollment for All NIH-Defined Phase III Clinical Trials Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Protocols	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/Alaska Native	% American Indian/Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	560,034	475	270,889	48.4	15,006	2.7	95,296	17.0	103,166	18.4	716	0.1	281,344	50.2
FY2009	486,563	434	266,605	54.8	17,509	3.6	92,868	19.1	116,233	23.9	859	0.2	189,527	39.0
FY2010	691,450	634	435,586	63.0	15,846	2.3	113,042	16.3	254,738	36.8	936	0.1	229,410	33.2
FY2011	583,119	579	347,757	59.6	26,035	4.5	179,062	30.7	89,538	15.4	1,043	0.2	213,182	36.6
FY2012	603,136	548	396,714	65.8	28,352	4.7	214,542	35.6	96,158	15.9	967	0.2	182,936	30.3

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	12,136	2.2	52,370	9.4
FY2009	4,676	1.0	64,891	13.3
FY2010	8,258	1.2	69,220	10.0
FY2011	7,668	1.3	66,591	11.4
FY2012	6,398	1.1	73,783	12.2

Table 4G: Total Enrollment for All NIH-Defined Phase III Clinical Trials Ethnic Categories

(New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	11,881,644	80.4	1,116,699	7.6	1,787,594	12.1
FY2009	16,033,547	85.5	1,302,944	6.9	1,412,781	7.5
FY2010	18,962,836	82.1	1,958,060	8.5	2,175,982	9.4
FY2011	12,687,228	79.4	1,641,383	10.3	1,645,551	10.3
FY2012	12,091,772	68.5	1,778,148	10.1	3,778,155	21.4

Table 4H: Total Enrollment for Domestic NIH-Defined Phase III Clinical Trials Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown /Other	% Unknown/ Other
FY2008	229,348	37,458	16.3	885	0.4	4,506	2.0	22,431	9.8	9,636	4.2	187,719	81.8	4,171	1.8
FY2009	150,439	24,468	16.3	569	0.4	2,861	1.9	14,768	9.8	6,270	4.2	122,713	81.6	3,258	2.2
FY2010	70,513	11,268	16.0	270	0.4	1,026	1.5	6,816	9.7	3,156	4.5	58,678	83.2	567	0.8
FY2011	929	12	1.3	1	0.1	2	0.2	9	1.0	0	0.0	882	94.9	35	3.8
FY2012	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 4I: Total Enrollment for Domestic NIH-Defined Phase III Clinical Trials Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/Alaska Native	% American Indian/Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	361,757	81,924	22.6	2,256	0.6	6,314	1.7	25,753	7.1	713	0.2	276,406	76.4
FY2009	283,456	72,611	25.6	5,349	1.9	11,752	4.1	23,520	8.3	844	0.3	183,320	64.7
FY2010	322,354	81,241	25.2	3,231	1.0	6,899	2.1	32,467	10.1	901	0.3	217,844	67.6
FY2011	302,987	76,403	25.2	3,390	1.1	7,720	2.5	27,134	9.0	1,014	0.3	204,315	67.4
FY2012	280,932	81,420	29.0	3,397	1.2	5,504	2.0	34,495	12.3	943	0.3	176,627	62.9

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	11,836	3.3	38,479	10.6
FY2009	4,672	1.6	53,999	19.1
FY2010	6,326	2.0	54,686	17.0
FY2011	6,142	2.0	53,272	17.6
FY2012	6,396	2.3	53,570	19.1

Table 4J: Total Enrollment for Domestic NIH-Defined Phase III Clinical Trials Ethnic Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	289,525	80.0	42,003	11.6	30,229	8.4
FY2009	212,327	74.9	32,101	11.3	39,028	13.8
FY2010	246,756	76.5	34,635	10.7	40,963	12.7
FY2011	230,759	76.2	34,308	11.3	37,920	12.5
FY2012	205,055	73.0	34,255	12.2	41,622	14.8

Table 4K: Total Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2008	226,137	36,952	16.3	880	0.4	4,442	2.0	22,069	9.8	9,561	4.2	185,032	81.8	4,153	1.8
FY2009	147,399	24,097	16.3	565	0.4	2,799	1.9	14,542	9.9	6,191	4.2	120,068	81.5	3,234	2.2
FY2010	67,454	10,894	16.2	265	0.4	963	1.4	6,586	9.8	3,080	4.6	56,016	83.0	544	0.8
FY2011	929	12	1.3	1	0.1	2	0.2	9	1.0	0	0.0	882	94.9	35	3.8
FY2012	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 4L: Total Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	358,886	80,917	22.5	2,449	0.7	6,192	1.7	24,843	6.9	636	0.2	275,071	76.6
FY2009	280,496	71,415	25.5	5,173	1.8	11,727	4.2	22,694	8.1	843	0.3	182,692	65.1
FY2010	315,544	78,112	24.8	2,947	0.9	6,700	2.1	30,058	9.5	900	0.3	213,988	67.8
FY2011	292,935	72,807	24.9	3,092	1.1	7,451	2.5	24,435	8.3	1,011	0.3	197,742	67.5
FY2012	270,082	77,371	28.6	3,091	1.1	5,207	1.9	31,609	11.7	938	0.3	169,553	62.8

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	11,832	3.3	37,863	10.6
FY2009	4,668	1.7	52,699	18.8
FY2010	6,321	2.0	54,630	17.3
FY2011	6,131	2.1	53,073	18.1
FY2012	6,377	2.4	53,307	19.7

Table 4M: Total Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials Ethnic Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	287,156	80.0	41,914	11.7	29,816	8.3
FY2009	209,846	74.8	31,936	11.4	38,714	13.8
FY2010	240,203	76.1	34,403	10.9	40,938	13.0
FY2011	221,136	75.5	33,942	11.6	37,857	12.9
FY2012	194,915	72.2	33,657	12.5	41,510	15.4

Table 4N: Total Enrollment for Domestic Intramural NIH-Defined Phase III Clinical Trials Racial Categories (Old Form, 1977 OMB Definitions) from FY2008-FY2012 (Five Year Trend)[20]

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic, not White	% Hispanic, not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2008	3,211	506	15.8	5	0.2	64	2.0	362	11.3	75	2.3	2,687	83.7	18	0.6
FY2009	3,040	371	12.2	4	0.1	62	2.0	226	7.4	79	2.6	2,645	87.0	24	0.8
FY2010	3,059	374	12.2	5	0.2	63	2.1	230	7.5	76	2.5	2,662	87.0	23	0.8
FY2011	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 4O: Total Enrollment for Domestic Intramural NIH-Defined Phase III Clinical Trials Racial Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Total Enrollment	Number of Minorities Enrolled	% of Minorities Enrolled	American Indian/Alaska Native	% American Indian/Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White
FY2008	2,871	1,207	42.0	7	0.2	122	4.2	910	31.7	77	2.7	1,335	46.5
FY2009	2,960	1,196	40.4	176	5.9	25	0.8	826	27.9	1	0.0	628	21.2
FY2010	6,810	3,129	45.9	284	4.2	199	2.9	2,409	35.4	1	0.0	3,856	56.6
FY2011	10,052	3,596	35.8	298	3.0	269	2.7	2,699	26.9	3	0.0	6,573	65.4
FY2012	10,850	4,049	37.3	306	2.8	297	2.7	2,886	26.6	5	0.0	7,074	65.2

Fiscal Year (FY)	More than one race	% More than one race	Unknown/Not Reported	% Unknown/Not Reported
FY2008	4	0.1	416	14.5
FY2009	4	0.1	1,300	43.9
FY2010	5	0.1	56	0.8
FY2011	11	0.1	199	2.0
FY2012	19	0.2	263	2.4

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[20] Data have zeroes for FY2011 and FY2012 because the intramural programs have migrated all data to the new data form (1997 OMB definitions)

Table 4P: Total Enrollment of Domestic Intramural NIH-Defined Phase III Clinical Trials Ethnic Categories (New Form, 1997 OMB Definitions) from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2008	2,369	82.5	89	3.1	413	14.4
FY2009	2,481	83.8	165	5.6	314	10.6
FY2010	6,553	96.2	232	3.4	25	0.4
FY2011	9,623	95.7	366	3.6	63	0.6
FY2012	10,140	93.5	598	5.5	112	1.0

Section 5: Metrics Based on Aggregate Enrollment: Sex/Gender by Race and Ethnicity for NIH Clinical Research

Table 5A: Minority Enrollment by Sex/Gender for All NIH Clinical Research from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	9,243,966	60.0	86,903	59.5	2,522,763	59.1
FY2008	**Male**	5,991,739	38.9	59,249	40.5	1,725,239	40.4
FY2008	**Unknown Sex/Gender**	176,650	1.1	19	0.0	17,933	0.4
FY2009	**Female**	3,438,992	59.5	38,109	51.1	3,400,883	59.6
FY2009	**Male**	2,325,402	40.2	36,455	48.9	2,288,947	40.0
FY2009	**Unknown Sex/Gender**	19,149	0.3	7	0.0	19,142	0.0
FY2010	**Female**	4,423,474	58.9	27,730	48.0	4,395,744	59.0
FY2010	**Male**	3,041,396	40.5	29,882	51.7	3,011,514	40.4
FY2010	**Unknown Sex/Gender**	45,893	0.6	143	0.2	45,750	0.6
FY2011	**Female**	4,018,450	62.3	1,619	49.8	4,016,831	62.3
FY2011	**Male**	2,430,139	37.7	2,204	67.8	2,427,935	37.7
FY2011	**Unknown Sex/Gender**	39,634	0.6	1	0.0	39,633	0.6
FY2012	**Female**	3,742,903	58.1	1,333	41.0	3,741,570	58.1
FY2012	**Male**	2,661,413	41.3	1,916	59.0	2,659,497	41.3
FY2012	**Unknown Sex/Gender**	41,859	0.6	1	0.0	41,858	0.6

Table 5B: FY2011 and FY2012 Enrollment for All NIH Clinical Research: Sex/Gender by Race (Old Form, 1977 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian/ Pacific Islander	% Asian/ Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	**Female**	28	0.3	192	2.3	676	8.1	723	8.7	6,545	78.6	167	2.0
FY2011	**Male**	32	0.3	189	1.9	1,111	11.2	872	8.8	7,402	74.5	332	3.3
FY2011	**Unknown Sex/Gender**	0	0.0	1	4.0	0	0.0	0	0.0	3	12.0	21	84.0
FY2012	**Female**	27	0.9	134	4.3	516	16.4	656	20.8	1,697	53.8	122	3.9
FY2012	**Male**	28	0.7	146	3.7	962	24.1	780	19.5	1,939	48.5	142	3.6
FY2012	**Unknown Sex/Gender**	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	13	92.9

Table 5C: FY2011 and FY2012 Enrollment for All NIH Clinical Research: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	215,720	2.3	1,607,044	16.9	1,181,791	12.5	27,304	0.3	5,342,673	56.3	197,882	2.1	918,937	9.7
FY2011	**Male**	144,147	2.3	732,466	11.7	911,489	14.5	20,374	0.3	3,790,071	60.4	150,575	2.4	528,246	8.4
FY2011	**Unknown Sex/Gender**	759	0.4	12,211	5.9	19,273	9.4	116	0.1	21,710	10.6	824	0.4	150,550	73.3
FY2012	**Female**	188,522	1.9	1,380,540	13.7	1,189,565	11.8	33,115	0.3	4,734,414	47.0	196,008	1.9	2,346,581	23.3
FY2012	**Male**	146,418	2.0	758,732	10.3	937,078	12.7	23,490	0.3	4,308,675	58.4	158,484	2.1	1,046,010	14.2
FY2012	**Unknown Sex/Gender**	520	0.3	17,964	9.0	13,998	7.0	116	0.1	27,439	13.7	1,047	0.5	139,359	69.5

Table 5D: FY2011 and FY2012 Enrollment for All NIH Clinical Research: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2011	**Female**	7,651,179	80.6	995,980	10.5	844,192	8.9
FY2011	**Male**	4,990,330	79.5	636,549	10.1	650,489	10.4
FY2011	**Unknown Sex/Gender**	45,719	22.3	8,854	4.3	150,870	73.4
FY2012	**Female**	6,490,049	64.5	967,926	9.6	2,610,770	25.9
FY2012	**Male**	5,544,566	75.1	801,398	10.9	1,032,923	14.0
FY2012	**Unknown Sex/Gender**	57,157	28.5	8,824	4.4	134,462	67.1

Table 5E: Minority Enrollment by Sex/Gender for Domestic NIH Clinical Research from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	2,121,057	60.2	86,451	77.3	2,034,606	59.7
FY2008	**Male**	1,386,456	39.4	25,121	22.5	1,361,335	39.9
FY2008	**Unknown Sex/Gender**	14,178	0.4	223	0.2	13,955	0.4
FY2009	**Female**	2,924,019	59.9	36,421	50.2	2,887,598	60.0
FY2009	**Male**	1,943,741	39.8	36,174	49.8	1,907,567	39.6
FY2009	**Unknown Sex/Gender**	16,034	0.3	6	0.0	16,028	0.3
FY2010	**Female**	3,557,029	58.9	25,909	46.9	3,531,120	59.0
FY2010	**Male**	2,444,784	40.5	29,177	52.8	2,415,607	40.4
FY2010	**Unknown Sex/Gender**	39,718	0.7	143	0.3	39,575	0.7
FY2011	**Female**	2,744,151	62.5	1,567	42.1	2,742,584	62.5
FY2011	**Male**	1,625,743	37.0	2,155	57.9	1,623,588	37.0
FY2011	**Unknown Sex/Gender**	20,870	0.5	1	0.0	20,869	0.5
FY2012	**Female**	2,423,584	55.9	1,333	41.0	2,422,251	56.0
FY2012	**Male**	1,882,114	43.4	1,916	59.0	1,880,198	43.4
FY2012	**Unknown Sex/Gender**	26,861	0.6	1	0.0	26,860	0.6

Table 5F: FY2011 and FY2012 Enrollment for Domestic NIH Clinical Research: Sex/Gender by Race (Old Form, 1977 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian/Pacific Islander	% Asian/Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	**Female**	28	0.3	190	2.3	647	7.9	702	8.6	6,420	78.9	155	1.9
FY2011	**Male**	32	0.3	189	1.9	1,083	11.2	851	8.8	7,242	74.6	316	3.3
FY2011	**Unknown Sex/Gender**	0	0.0	1	4.3	0	0.0	0	0.0	1	4.3	21	91.3
FY2012	**Female**	27	0.9	134	4.3	516	16.4	656	20.8	1,697	53.8	122	3.9
FY2012	**Male**	28	0.7	146	3.7	962	24.1	780	19.5	1,939	48.5	142	3.6
FY2012	**Unknown Sex/Gender**	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	13	92.9

Table 5G: FY2011 and FY2012 Enrollment for Domestic NIH Clinical Research: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown /Not Reported	% Unknown /Not Reported
FY2011	**Female**	99,355	1.2	900,326	11.3	883,925	11.1	27,038	0.3	5,087,456	63.9	185,336	2.3	783,380	9.8
FY2011	**Male**	53,107	1.0	331,188	6.2	714,528	13.5	20,093	0.4	3,625,113	68.3	139,495	2.6	421,715	7.9
FY2011	**Unknown Sex/Gender**	604	0.3	3,077	1.7	11,892	6.6	116	0.1	18,741	10.4	782	0.4	145,124	80.5
FY2012	**Female**	66,154	0.8	662,431	7.8	887,422	10.5	32,962	0.4	4,465,700	52.6	179,017	2.1	2,193,947	25.8
FY2012	**Male**	56,695	0.9	363,506	5.7	767,298	12.0	23,396	0.4	4,107,877	64.1	149,024	2.3	936,416	14.6
FY2012	**Unknown Sex/Gender**	480	0.3	8,058	4.5	10,796	6.0	116	0.1	25,018	14.0	1,009	0.6	133,275	74.6

Table 5H: FY2011 and FY2012 Enrollment for Domestic NIH Clinical Research: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2011	**Female**	6,453,744	81.0	721,924	9.1	791,148	9.9
FY2011	**Male**	4,282,102	80.7	422,490	8.0	600,647	11.3
FY2011	**Unknown Sex/Gender**	30,122	16.7	6,675	3.7	143,539	79.6
FY2012	**Female**	5,246,806	61.8	671,787	7.9	2,569,040	30.3
FY2012	**Male**	4,825,831	75.4	584,353	9.1	994,028	15.5
FY2012	**Unknown Sex/Gender**	42,748	23.9	6,982	3.9	129,022	72.2

Table 5I: Minority Enrollment by Sex/Gender for Domestic Extramural NIH Clinical Research from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	1,946,882	63.0	47,117	67.1	1,899,765	62.9
FY2008	**Male**	1,131,742	36.6	23,032	32.8	1,108,710	36.7
FY2008	**Unknown Sex/Gender**	13,841	0.4	19	0.0	13,822	0.5
FY2009	**Female**	2,697,251	62.8	15,710	45.5	2,681,541	62.8
FY2009	**Male**	1,595,146	37.2	18,821	54.5	1,576,325	36.9
FY2009	**Unknown Sex/Gender**	1,211	0.0	3	0.0	12,109	0.3
FY2010	**Female**	3,304,953	60.9	4,986	29.6	3,299,967	61.0
FY2010	**Male**	2,084,271	38.4	11,718	69.6	2,072,553	38.3
FY2010	**Unknown Sex/Gender**	34,070	0.6	139	0.8	33,931	0.6
FY2011	**Female**	2,478,812	66.2	1,567	42.1	2,477,245	66.2
FY2011	**Male**	1,254,173	33.5	2,155	57.9	1,252,018	33.5
FY2011	**Unknown Sex/Gender**	13,682	0.4	1	0.0	13,681	0.4
FY2012	**Female**	2,128,669	58.6	1,333	41.0	2,127,336	58.6
FY2012	**Male**	1,480,077	40.7	1,916	59.0	1,478,161	40.7
FY2012	**Unknown Sex/Gender**	25,354	0.7	1	0.0	25,353	0.7

Table 5J: FY2011 and FY2012 Enrollment for Domestic Extramural NIH Clinical Research: Sex/Gender by Race (Old Form, 1977 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian/Pacific Islander	% Asian/Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	**Female**	28	0.3	190	2.3	647	7.9	702	8.6	6,420	78.9	155	1.9
FY2011	**Male**	32	0.3	189	1.9	1,083	11.2	851	8.8	7,242	74.6	316	3.3
FY2011	**Unknown Sex/Gender**	0	0.0	1	4.3	0	0.0	0	0.0	1	4.3	21	91.3
FY2012	**Female**	27	0.9	134	4.3	516	16.4	656	20.8	1,697	53.8	122	3.9
FY2012	**Male**	28	0.7	146	3.7	962	24.1	780	19.5	1,939	48.5	142	3.6
FY2012	**Unknown Sex/Gender**	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	13	92.9

Table 5K: FY2011 and FY2012 Enrollment for Domestic Extramural NIH Clinical Research: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	87,237	1.3	874,313	12.6	786,178	11.3	24,616	0.4	4,388,684	63.1	108,137	1.6	683,934	9.8
FY2011	**Male**	40,101	1	305,047	8	504,320	13	17,823	0	2,584,091	69	70,006	2	248,218	7
FY2011	**Unknown Sex/Gender**	576	0.5	3,045	2.7	4,816	4.3	115	0.1	13,786	12.2	768	0.7	89,913	79.6
FY2012	**Female**	53,419	0.9	630,562	10.2	780,065	12.6	30,096	0.5	3,715,392	60.2	101,137	1.6	859,285	13.9
FY2012	**Male**	43,046	0.9	331,040	6.9	550,500	11.5	20,728	0.4	3,001,289	63.0	78,915	1.7	740,921	15.5
FY2012	**Unknown Sex/Gender**	474	0.4	7,844	6.4	9,595	7.8	115	0.1	19,867	16.1	992	0.8	84,262	68.4

Table 5L: FY2011 and FY2012 Enrollment for Domestic Extramural NIH Clinical Research: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2011	**Female**	5,654,058	81.3	669,615	9.6	629,426	9.1
FY2011	**Male**	3,042,902	81	368,001	10	358,703	10
FY2011	**Unknown Sex/Gender**	18,066	16.0	6,636	5.9	88,317	78.1
FY2012	**Female**	4,425,687	71.7	607,349	9.8	1,136,920	18.4
FY2012	**Male**	3,585,665	75.2	514,185	10.8	666,589	14.0
FY2012	**Unknown Sex/Gender**	36,435	29.6	6,908	5.6	79,806	64.8

Table 5M: Minority Enrollment by Sex/Gender for Domestic Intramural NIH Clinical Research from FY2008-FY2012 (Five Year Trend)[21]

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	172,273	37.5	39,295	52.4	132,978	34.6
FY2008	**Male**	286,978	62.5	35,663	47.6	251,315	65.4
FY2008	**Unknown Sex/Gender**	109	0.0	0	0.0	109	0.0
FY2009	**Female**	226,768	39.1	20,711	54.4	206,057	38.1
FY2009	**Male**	348,595	60.2	17,353	45.6	331,242	61.2
FY2009	**Unknown Sex/Gender**	3,922	0.7	3	0.0	3,919	0.7
FY2010	**Female**	252,076	40.8	20,923	54.5	231,153	39.9
FY2010	**Male**	360,513	58.3	17,459	45.5	343,054	59.2
FY2010	**Unknown Sex/Gender**	5,648	0.9	4	0.0	5,644	1.0
FY2011	**Female**	265,339	41.2	0	0.0	265,339	41.2
FY2011	**Male**	371,570	57.7	0	0.0	371,570	57.7
FY2011	**Unknown Sex/Gender**	7,188	1.1	0	0.0	7,188	1.1
FY2012	**Female**	294,915	42.2	0	0.0	294,915	42.2
FY2012	**Male**	402,037	57.6	0	0.0	402,037	57.6
FY2012	**Unknown Sex/Gender**	1,507	0.2	0	0.0	1,507	0.2

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[21] Data have zeroes for FY2011 and FY2012 because the intramural programs have migrated all data to the new data form (1997 OMB definitions)

Table 5N: FY2011 and FY2012 Enrollment for Domestic Intramural NIH Clinical Research: Sex/Gender by Race (Old Form, 1977 OMB Definitions)[22]

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian/Pacific Islander	% Asian/Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	**Female**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2011	**Male**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2011	**Unknown Sex/Gender**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Female**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Male**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Unknown Sex/Gender**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 5O: FY2011 and FY2012 Enrollment for Domestic Intramural NIH Clinical Research: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	12,118	1.2	26,013	2.6	97,747	9.6	2,422	0.2	698,772	68.9	77,199	7.6	99,446	9.8
FY2011	**Male**	13,006	1	26,141	2	210,208	14	2,270	0	1,041,022	68	69,489	5	173,497	11.3
FY2011	**Unknown Sex/Gender**	28	0.0	32	0.0	7,076	10.5	1	0.0	4,955	7.4	14	0.0	55,211	82.0
FY2012	**Female**	12,735	0.5	31,869	1.4	107,357	4.6	2,866	0.1	750,308	32.4	77,880	3.4	1,334,662	57.6
FY2012	**Male**	13,649	0.8	32,466	2.0	216,798	13.2	2,668	0.2	1,106,588	67.6	70,109	4.3	195,495	11.9
FY2012	**Unknown Sex/Gender**	6	0.0	214	0.4	1,201	2.2	1	0.0	5,151	9.3	17	0.0	49,013	88.1

Table 5P: FY2011 and FY2012 Enrollment for Domestic Intramural NIH Clinical Research: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/ Not Reported
FY2011	**Female**	799,686	78.9	52,309	5.2	161,722	16.0
FY2011	**Male**	1,239,200	122	54,489	4	241,944	15.8
FY2011	**Unknown Sex/Gender**	12,056	1.2	39	0.1	55,222	82.0
FY2012	**Female**	821,119	35.4	64,438	2.8	1,432,120	61.8
FY2012	**Male**	1,240,166	75.7	70,168	4.3	327,439	20.0
FY2012	**Unknown Sex/Gender**	6,313	11.4	74	0.1	49,216	88.5

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[22] Data have zeroes because the intramural programs have migrated all data to the new data form (1997 OMB definitions)

Section 6: Metrics Based on Aggregate Enrollment: Sex/Gender by Race and Ethnicity
NIH-Defined Phase III Clinical Trials

Table 6A: Minority Enrollment by Sex/Gender for All NIH-Defined Phase III Clinical Trials from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	169,540	55.0	23,466	62.5	146,074	53.9
FY2008	**Male**	137,983	44.7	14,062	37.5	123,921	45.7
FY2008	**Unknown Sex/Gender**	895	0.3	1	0.0	894	0.3
FY2009	**Female**	157,952	54.1	11,213	44.2	146,739	55.0
FY2009	**Male**	133,282	45.7	14,129	55.7	119,153	44.7
FY2009	**Unknown Sex/Gender**	715	0.2	2	0.0	713	0.3
FY2010	**Female**	250,716	56.1	2,741	23.6	247,975	56.9
FY2010	**Male**	195,249	43.7	8,860	76.4	186,389	42.8
FY2010	**Unknown Sex/Gender**	1,222	0.3	0	0.0	1,222	0.3
FY2011	**Female**	214,756	61.8	6	46.2	214,750	61.8
FY2011	**Male**	130,546	37.5	7	53.8	130,539	37.5
FY2011	**Unknown Sex/Gender**	2,468	0.7	0	0.0	2,468	0.7
FY2012	**Female**	273,477	68.9	0	0.0	273,477	68.9
FY2012	**Male**	118,517	29.9	0	0.0	118,517	29.9
FY2012	**Unknown Sex/Gender**	4,720	1.2	0	0.0	4,720	1.2

Table 6B: FY2011 and FY2012 Enrollment for All NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (Old Form, 1977 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian/Pacific Islander	% Asian/Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	**Female**	1	0.2	3	0.6	2	0.4	0	0.0	468	94.2	23	4.6
FY2011	**Male**	0	0.0	0	0.0	7	1.1	0	0.0	617	93.6	35	5.3
FY2011	**Unknown Sex/Gender**	0	0	0	0	0	0	0	0	3	0.455235	0	0.0
FY2012	**Female**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Male**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Unknown Sex/Gender**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 6C: FY2011 and FY2012 Enrollment for All NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	15,546	4.7	109,835	33.0	55,397	16.6	553	0.2	121,282	36.4	2,995	0.9	27,188	8.2
FY2011	**Male**	10,424	4.7	67,414	30.4	33,897	15.3	483	0.2	90,997	41.1	4,602	2.1	13,584	6.1
FY2011	**Unknown Sex/Gender**	65	0.2	1,813	6.3	244	0.8	7	0.0	903	3.1	71	0.2	25,819	89.3
FY2012	**Female**	20,461	5.5	147,568	39.4	67,023	17.9	482	0.1	103,716	27.7	3,252	0.9	32,317	8.6
FY2012	**Male**	7,854	4.0	63,009	32.0	28,797	14.6	478	0.2	78,254	39.7	3,073	1.6	15,554	7.9
FY2012	**Unknown Sex/Gender**	37	0.1	3,965	12.7	338	1.1	7	0.0	966	3.1	73	0.2	25,912	82.8

Table 6D: FY2011 and FY2012 Enrollment for All NIH-Defined Phase III Clinical Trials: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	277,170	83.3	45,823	13.8	9,803	2.9
FY2011	**Male**	185,527	83.8	25,827	11.7	10,047	4.5
FY2011	**Unknown Sex/Gender**	3,017	10.4	348	1.2	25,557	88.4
FY2012	**Female**	310,773	82.9	55,079	14.7	8,967	2.4
FY2012	**Male**	161,842	82.1	23,366	11.9	11,811	6.0
FY2012	**Unknown Sex/Gender**	5,293	16.9	352	1.1	25,653	82.0

Table 6E: Minority Enrollment by Sex/Gender for Domestic NIH-Defined Phase III Clinical Trials from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	68,672	57.4	23,397	62.5	45,275	55.1
FY2008	**Male**	50,392	42.1	14,060	37.5	36,332	44.2
FY2008	**Unknown Sex/Gender**	518	0.4	1	0.0	517	0.6
FY2009	**Female**	58,301	60.1	10,580	43.2	47,721	65.7
FY2009	**Male**	38,266	39.4	13,887	56.8	24,379	33.6
FY2009	**Unknown Sex/Gender**	512	0.5	1	0.0	511	0.7
FY2010	**Female**	52,003	56.2	2,522	22.4	49,481	60.9
FY2010	**Male**	40,099	43.3	8,746	77.6	31,353	38.6
FY2010	**Unknown Sex/Gender**	407	0.4	0	0.0	407	0.5
FY2011	**Female**	46,895	61.4	5	41.7	46,890	61.4
FY2011	**Male**	29,040	38.0	7	58.3	29,033	38.0
FY2011	**Unknown Sex/Gender**	480	0.6	0	0.0	480	0.6
FY2012	**Female**	48,783	59.9	0	0.0	48,783	59.9
FY2012	**Male**	32,106	39.4	0	0.0	32,106	39.4
FY2012	**Unknown Sex/Gender**	531	0.7	0	0.0	531	0.7

Table 6F: FY2011 and FY2012 Enrollment for Domestic NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (Old Form, 1977 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian/Pacific Islander	% Asian/Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	**Female**	1	0.0	2	0.0	2	0.0	0	0.0	372	0.0	12	0.0
FY2011	**Male**	0	0.0	0	0.0	7	0.0	0	0.0	509	0.0	23	0.0
FY2011	**Unknown Sex/Gender**	0	0.0	0	0.0	0	0.0	0	0.0	1	0.0	0	0.0
FY2012	**Female**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Male**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Unknown Sex/Gender**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 6G: FY2011 and FY2012 Enrollment for Domestic NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	1,820	1.1	4,857	3.0	17,929	11.2	539	0.3	116,491	72.7	2,991	1.9	15,628	9.8
FY2011	**Male**	1,542	1.3	2,822	2.4	9,138	7.9	468	0.4	86,926	75.1	3,080	2.7	11,830	10.2
FY2011	**Unknown Sex/Gender**	28	0.1	41	0.2	67	0.2	7	0.0	898	3.3	71	0.3	25,814	95.9
FY2012	**Female**	1,821	1.2	3,091	2.1	21,849	14.9	471	0.3	100,857	68.6	3,250	2.2	15,652	10.6
FY2012	**Male**	1,548	1.4	2,371	2.2	12,549	11.7	465	0.4	74,810	70.0	3,073	2.9	12,026	11.3
FY2012	**Unknown Sex/Gender**	28	0.1	42	0.2	97	0.4	7	0.0	960	3.5	73	0.3	25,892	95.5

Table 6H: FY2011 and FY2012 Enrollment for Domestic NIH-Defined Phase III Clinical Trials: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	132,640	82.8	20,393	12.7	7,222	4.5
FY2011	**Male**	97,050	83.8	13,606	11.7	5,150	4.4
FY2011	**Unknown Sex/Gender**	1,069	4.0	309	1.1	25,548	94.9
FY2012	**Female**	119,053	81.0	20,066	13.7	7,872	5.4
FY2012	**Male**	84,873	79.4	13,862	13.0	8,107	7.6
FY2012	**Unknown Sex/Gender**	1,129	4.2	327	1.2	25,643	94.6

Table 6I: Minority Enrollment by Sex/Gender for Domestic Extramural NIH-Defined Phase III Clinical Trials from FY2008-FY2012 (Five Year Trend)

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	67,801	57.5	23,224	62.8	44,577	55.1
FY2008	**Male**	49,563	42.0	13,727	37.1	35,836	44.3
FY2008	**Unknown Sex/Gender**	505	0.4	1	0.0	504	0.6
FY2009	**Female**	57,483	60.2	10,461	43.4	47,022	65.8
FY2009	**Male**	37,530	39.3	13,635	56.6	23,895	33.5
FY2009	**Unknown Sex/Gender**	499	0.5	1	0.0	498	0.7
FY2010	**Female**	49,166	55.2	2,402	22.0	46,764	59.9
FY2010	**Male**	39,446	44.3	8,492	78.0	30,954	39.6
FY2010	**Unknown Sex/Gender**	394	0.4	0	0.0	394	0.5
FY2011	**Female**	43,996	60.4	5	41.7	43,991	60.4
FY2011	**Male**	28,356	38.9	7	58.3	28,349	38.9
FY2011	**Unknown Sex/Gender**	467	0.6	0	0.0	467	0.6
FY2012	**Female**	45,421	58.7	0	0.0	45,421	58.7
FY2012	**Male**	31,432	40.6	0	0.0	31,432	40.6
FY2012	**Unknown Sex/Gender**	518	0.7	0	0.0	518	0.7

Table 6J: FY2011 and FY2012 Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (Old Form, 1977 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian/Pacific Islander	% Asian/Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic, not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	**Female**	1	0.0	2	0.0	2	0.0	0	0.0	372	0.0	12	0.0
FY2011	**Male**	0	0.0	0	0.0	7	0.0	0	0.0	509	0.0	23	0.0
FY2011	**Unknown Sex/Gender**	0	0.0	0	0.0	0	0.0	0	0.0	1	0.0	0	0.0
FY2012	**Female**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Male**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	**Unknown Sex/Gender**	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 6K: FY2011 and FY2012 Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	**Female**	1,578	1.0	4,658	3.0	15,727	10.3	538	0.4	111,919	73.2	2,983	2.0	15,514	10.1
FY2011	**Male**	1,486	1.3	2,752	2.4	8,654	7.7	466	0.4	84,925	75.1	3,077	2.7	11,745	10.4
FY2011	**Unknown Sex/Gender**	28	0.1	41	0.2	54	0.2	7	0.0	898	3.3	71	0.3	25,814	95.9
FY2012	**Female**	1,575	1.1	2,863	2.1	19,453	14.0	468	0.3	95,753	69.0	3,237	2.3	15,462	11.1
FY2012	**Male**	1,488	1.4	2,302	2.2	12,072	11.6	463	0.4	72,840	69.9	3,067	2.9	11,953	11.5
FY2012	**Unknown Sex/Gender**	28	0.1	42	0.2	84	0.3	7	0.0	960	3.5	73	0.3	25,892	95.6

Table 6L: FY2011 and FY2012 Enrollment for Domestic Extramural NIH-Defined Phase III Clinical Trials: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2011	**Female**	125,630	82.2	20,098	13.1	7,189	4.7
FY2011	**Male**	94,450	83.5	13,535	12.0	5,120	4.5
FY2011	**Unknown Sex/Gender**	1,056	3.9	309	1.1	25,548	94.9
FY2012	**Female**	111,487	80.3	19,532	14.1	7,792	5.6
FY2012	**Male**	82,312	79.0	13,798	13.2	8,075	7.8
FY2012	**Unknown Sex/Gender**	1,116	4.1	327	1.2	25,643	94.7

Table 6M: Minority Enrollment by Sex/Gender for Domestic Intramural NIH-Defined Phase III Clinical Trials from FY2008-FY2012 (Five Year Trend)[23]

Fiscal Year (FY)	Sex/Gender	Total Number of Minorities Enrolled	% of Minorities Enrolled	Number of Minorities Enrolled and Reported on OLD Form	% of Minorities Enrolled and Reported on OLD Form	Number of Minorities Enrolled and Reported on NEW Form	% of Minorities Enrolled and Reported on NEW Form
FY2008	**Female**	871	50.8	173	34.2	698	57.8
FY2008	**Male**	829	48.4	333	65.8	496	41.1
FY2008	**Unknown Sex/Gender**	13	0.8	0	0.0	13	1.1
FY2009	**Female**	818	52.2	119	32.1	699	58.4
FY2009	**Male**	736	47.0	252	67.9	484	40.5
FY2009	**Unknown Sex/Gender**	13	0.8	0	0.0	13	1.1
FY2010	**Female**	2,837	81.0	120	32.1	2,717	86.8
FY2010	**Male**	653	18.6	254	67.9	399	12.8
FY2010	**Unknown Sex/Gender**	13	0.4	0	0.0	13	0.4
FY2011	**Female**	2,899	80.6	0	0.0	2,899	80.6
FY2011	**Male**	684	19.0	0	0.0	684	19.0
FY2011	**Unknown Sex/Gender**	13	0.4	0	0.0	13	0.4
FY2012	**Female**	3,362	83.0	0	0.0	3,362	83.0
FY2012	**Male**	674	16.6	0	0.0	674	16.6
FY2012	**Unknown Sex/Gender**	13	0.3	0	0.0	13	0.3

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[23] Data have zeroes for FY2011 and FY2012 because the intramural programs have migrated all data to the new data form (1997 OMB definitions)

Table 6N: FY2011 and FY2012 Enrollment for Domestic Intramural NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (Old Form, 1977 OMB Definitions)[24]

Fiscal Year (FY)	Sex/Gender	American Indian/Alaska Native	% American Indian/Alaska Native	Asian/Pacific Islander	% Asian/Pacific Islander	Black or African American	% Black or African American	Hispanic not White	% Hispanic not White	White	% White	Unknown/ Other	% Unknown/ Other
FY2011	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2011	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2011	Unknown Sex/Gender	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	Unknown Sex/Gender	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 6O: FY2011 and FY2012 Enrollment for Domestic Intramural NIH-Defined Phase III Clinical Trials: Sex/Gender by Race (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	American Indian/ Alaska Native	% American Indian/ Alaska Native	Asian	% Asian	Black or African American	% Black or African American	Native Hawaiian or Pacific Islander	% Native Hawaiian or Pacific Islander	White	% White	More than one race	% More than one race	Unknown/ Not Reported	% Unknown/ Not Reported
FY2011	Female	242	3.3	199	2.7	2,202	30.0	1	0.0	4,572	62.3	8	0.1	114	1.6
FY2011	Male	56	2.1	70	2.6	484	17.9	2	0.1	2,001	74.1	3	0.1	85	3.1
FY2011	Unknown Sex/Gender	0	0.0	0	0.0	13	100.0	0	0.0	0	0.0	0	0.0	0	0.0
FY2012	Female	246	3.0	228	2.8	2,396	29.3	3	0.0	5,104	62.4	13	0.2	190	2.3
FY2012	Male	60	2.3	69	2.6	477	18.0	2	0.1	1,970	74.1	6	0.2	73	2.7
FY2012	Unknown Sex/Gender	0	0.0	0	0.0	13	100.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 6P: FY2011 and FY2012 Enrollment for Domestic Intramural NIH-Defined Phase III Clinical Trials: Sex/Gender by Ethnicity (New Form, 1997 OMB Definitions)

Fiscal Year (FY)	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic or Latino	% Hispanic or Latino	Unknown/Not Reported	% Unknown/Not Reported
FY2011	Female	7,010	95.5	295	4.0	33	0.4
FY2011	Male	2,600	96.3	71	2.6	30	1.1
FY2011	Unknown Sex/Gender	13	100.0	0	0.0	0	0.0
FY2012	Female	7,566	92.5	534	6.5	80	1.0
FY2012	Male	2,561	96.4	64	2.4	32	1.2
FY2012	Unknown Sex/Gender	13	100.0	0	0.0	0	0.0

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[24] Data have zeroes because the intramural programs have migrated all data to the new data form (1997 OMB definitions)

Appendix B

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 supersedes 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 provides 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, is 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://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html 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.

Appendix C

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/directive_15.html.

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

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

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

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

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

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

Ethnic Categories:

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

Not Hispanic or Latino

Racial Categories:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Annual Progress Reports (type 5) and Competing Supplement Applications

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

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

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

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

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

III. Frequently Asked Questions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix D: Glossary of Important Terms for Inclusion

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

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies;
(2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research. Note: This definition excludes projects that qualify for IRB Exemption #4.

NIH-Defined Phase III Clinical Trial

For the purpose of these guidelines, a NIH-defined "Phase III clinical trial" is a broadly based prospective 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.