Department of Health and Human Services
National Institutes of Health

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

Comprehensive Report: Tracking of Human Subjects Research As Reported in Fiscal Year 2003 and Fiscal Year 2004

NIH Tracking/Inclusion Committee

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

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

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

Carlos E. Caban, Ph.D.
Liaison, Office of Extramural Research

Kim Jarema
Liaison, Office of Intramural Research

2005

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Historical Background

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

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

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

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

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

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

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

A variety of outreach activities were initiated to explain the revised policy to the scientific research community and to clear up common misunderstandings about the new requirements. Recognizing the importance of both recruitment and retention of human subject volunteers, NIH issued several articles(9-10) and an outreach notebook, entitled *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research*, that outlines elements of outreach processes, offers practical suggestions, and provides references to additional sources of information. The outreach notebook is available on the Office of Research on Women's Health Website http://www4.od.nih.gov/orwh/outreach.pdf. It also includes the full text of the 1994 implementation guidelines as well as a questions and answers document to provide more detailed policy guidance and some of the more commonly asked questions. The ORWH also has available a full report of its workshop on "Recruitment and Retention of Women in Clinical Studies."

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

Continuing Implementation and Monitoring Activities: 2000 to the Present

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

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

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

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

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

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

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

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

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

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

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

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

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

  - As part of an NIH Symposium: Human Subjects Update, the revised policy on inclusion of women and minorities and the revised NIH Instructions to Reviewers Guidelines for Evaluating the Inclusion of Women and Minorities as Subjects in Clinical Research were used as the basis for a required training session for NIH staff. The revised training materials are permanently archived in the training materials for NIH staff at: http://odoerdb2.od.nih.gov/oer/training/esa/human_subjects/esa_hs_symposium.htm.

  - An additional training session regarding a Grants Policy Update: Humans and Animals was held in December, 2000 where several hundred additional extramural and intramural researchers were trained. Additional training materials addressing the inclusion of human subjects can be found at the following web address:

    http://odoerdb2.od.nih.gov/oer/training/esa/grants_policy_update/esa_grants_policy_update.htm.

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

- The PHS 398 Grant Application was significantly revised to provide additional instructions about the Women and Minorities Inclusion Policy and the revised form will be mandatory beginning May 10, 2005.

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

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

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

- In 2003, the ORWH sponsored a workshop entitled, "Science Meets Reality: Recruitment and Retention of Women in Clinical Studies, and the Critical Role of Relevance." This workshop discussed lessons learned, continuing challenges and emerging ethical and policy issues concerning the recruitment and retention of women and other participants in clinical studies over the past decade.

The Office of Extramural Research (OER) has made available existing training materials on the Population tracking system website on the NIH Intranet. Information include: the training workbook, "Sex/Gender and Minority Inclusion in Clinical Research", a series of quick tips and case examples as well as the Help section of the Population Tracking module itself. A training subcommittee of the full NIH Tracking and Inclusion committee has been established to develop new training documents and methods of training for NIH staff and the extramural research community.

Major changes have been made to the Population tracking system to help NIH staff in monitoring compliance with the NIH Inclusion policy. For example, the Population Tracking Grant Snapshot report was revised to provide easy access for NIH staff to the population data. Additionally, several Population Inclusion reports were added to the NIH Query View Report (QVR) system, thus providing broader access to the data. As well, user roles were revised and expanded to all the Division of Extramural Activities Support (DEAS) staff to assist in the data entry functions.

Communication and Outreach Efforts to the Scientific Community

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

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

- The *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research* was published in the fall of 2002 and is available to the research community and NIH staff. This publication discusses the elements of recruitment and retention, the NIH inclusion policy, 1997 OMB requirements for reporting race and ethnicity data, as well as information for application submission, peer review, and funding. The publication is posted on the ORWH website http://www4.od.nih.gov/orwh as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm .

- In addition, the *Frequently Asked Questions (FAQs) for the Inclusion , Recruitment and Retention of Women and Minority Subjects in Clinical Research* complements the *Outreach Notebook* and provides additional guidance to researchers and NIH staff in a user friendly format. The *FAQs* is posted on the ORWH website http://www4.od.nih.gov/orwh as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm.

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

Monitoring Compliance: Extramural and Intramural Population Data Analysis

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

NIH has monitored aggregate demographic data for study populations through the existing NIH computerized tracking system since fiscal year 1994 and tracking the inclusion of women and minorities in clinical studies has been implemented in all ICs. The NIH Tracking and Inclusion Committee continues to work on ways to refine and improve data collection methods and the quality of the data entered by each IC into this system. In May 2002, the NIH successfully deployed a new population tracking system for monitoring the inclusion of women and minorities in clinical research. This system provides easier data entry and project monitoring for NIH staff, creates clear and timely NIH reports on inclusion data, incorporates the 1997 OMB Office of Management and Budget (OMB) standards for the classification of federal data on race and ethnicity, and is consistent with the newly revised PHS Form 398 and PHS Form 2590 (revised May, 2001). Following the implementation of the population tracking module, an *eRA Population Tracking User Group* consisting of representatives from several ICs, was formed to evaluate the system, recommend improvements and modifications, and provide continuous feedback related to system use. The re-engineered population tracking system continues to be refined based on input from the NIH user community.

- NIH has published an on-line users guide and began offering 2-hour Population Tracking System demonstrations as well as in-depth, hands-on training sessions on the use of the population tracking system.

The aggregate data enable the NIH to measure inclusion in order to formulate more specific questions about gaps in enrollment and to design studies to respond to those questions. Data compiled in future years will allow for longitudinal examination of trends and continued monitoring of compliance.

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

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

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

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

Conclusion and Current Status

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

In addition, the section of this report entitled, "Part II: Biennial Institute and Center Advisory Council Reports Certifying Compliance with Inclusion Guidelines, Spring 2005," provides statements from the Advisory Councils of each IC resulting from discussions and certification of the compliance of each IC with the NIH overall inclusion policies.

Finally, the dedication and tireless commitment of the IC representatives to the NIH Tracking and Inclusion Committee must be acknowledged with appreciation for their efforts.

VWP

References

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

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

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

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

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

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

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

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

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

4. Office of Research on Women's Health Website: http://www4.od.nih.gov/orwh/fy97-98trkg.pdf

Aggregate Enrollment Data Tables For Extramural and Intramural Research Protocols

Fiscal Years 2003 & 2004

Summary Report of NIH Inclusion Data

NIH Aggregate Extramural and Intramural Population Data Reported in FY 2003 and FY 2004

Tables 1 to 29 provide aggregate enrollment data for extramural and intramural research protocols funded in FY 2003 and FY 2004. Previous inclusion reports and aggregate enrollment figures for women, men and minority groups for FY 1994 to the present can be found on the ORWH website at http://od.nih.gov/orwh/inclusion.html. For this Biennial Report, the FY 2003 and FY2004 data tables have been reformatted and some tables may vary slightly from prior reported summary data. Some additional data has been presented.

Analysis of the FY 2003 and FY 2004 inclusion data show that substantial numbers of women, non-minority men, and minorities have been included as research subjects in Phase III clinical trials and other human subject research studies, in both intramural and extramural programs.

EXTRAMURAL RESEARCH: Fiscal Years 2003 and 2004

In FY 2003, over 12 million participants were reported for all extramural clinical research, including Phase III clinical trials and other clinical studies. A snapshot of the aggregate enrollment data shows that approximately 60% were women, 39.9% were men, and 0.9% did not identify a sex/gender. (*Table 9*) Correspondingly, in FY 2004, over 16 million participants were reported for all extramural clinical research, including Phase III clinical trials and other clinical studies, an increase of about 4 million participants. Of the 16 million participants, approximately 58.6% were women, 39.8% were men, and 1.6% did not provide sex identification. (*Table 11*) While the number of participants in clinical research significantly increased, there was no substantial percentage change in the ratio of women and men. However, when sex-specific studies were excluded the proportions of women and men in all clinical research were proportional to the percentages of the general population. *(See Tables 10 & 12)*

Aggregate enrollment data reported in FY 2003 for extramural Phase III trials show that approximately 55.4% of the participants were women. Of the 635 extramural Phase III research protocols that continue to report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 11.6% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics comprised approximately 6.7%, Asian/Pacific Islanders 1.83% and Whites (not Hispanic) 77.2% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards and therefore, no data were reported in these categories. (*Table 13*)

In FY 2003 there were 196 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 28.3% and lowest for Hawaiian/Pacific Islanders at 0.2%. Asians represented 2.71%, American Indian/Alaska Natives 0.53% and White 57.1%. 1.04% of the participants identified *More Than One Race* for their racial category. Of the 196 extramural Phase III research protocols designating an ethnicity in FY 2003, 77.5% identified a racial category and an ethnicity of not Hispanic. Whereas, 9.71% identified a racial category and an ethnic category of Hispanic/Latino. 13.7% of participants identified a racial category but did not report an ethnicity. (*Table 13*)

Aggregate enrollment data for extramural Phase III trials reported in FY 2004 show that approximately 55.9% were women. Of the 273 extramural Phase III research protocols that continue to report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7%, Asian/Pacific Islanders were 1.9% and Whites (not Hispanic) 76% of the participants. The categories

Hawaiian/Pacific Islander and *More Than One Race* were not designations with the 1977 OMB standards and therefore, no data were reported in these categories. (*Table 15*)

In FY 2004, there were 266 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 24.3% and lowest for Hawaiian/Pacific Islanders 0.3%. Asians represented 2.46%, American Indian/Alaska Natives 0.8% and Whites 66.5% of participants. Participants identifying as *More Than One* Race were 2.6% of the total number of participants. Of the 266 extramural Phase III research protocols designating an ethnicity in FY 2004, 86.4% identified a racial category and an ethnicity of not Hispanic. Whereas, 8.5% identified a racial category and an ethnic category of Hispanic/Latino. 5% of participants identified a racial category but did not report an ethnicity. (*Table 15*)

INTRAMURAL RESEARCH: Fiscal Years 2003 and 2004

Substantial numbers of women and minorities were included in NIH intramural studies in FY 2003 and FY2004. In FY 2003, approximately 1.8 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Approximately 47.5% were women, 51.7% were men and 0.8% did not identify their sex. Of the 951 intramural research protocols that continue to report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 10.5% and lowest for American Indian/Alaska Natives at 1%. Blacks (not Hispanic) represented approximately 5.6%; Hispanics 3.2%; and Whites (not Hispanic) 72.6% of the intramural research study population. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards and therefore, no data were reported in these categories. (*Table 17*)

For all intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2003, the largest racial minority group was Blacks at 17.3% and the smallest racial minority group was Hawaiian/Pacific Islanders at .03%. Asians represented 5.8%, American Indian/Alaska Natives 0.4% and Whites 70.5% of participants in all intramural clinical research. Approximately 0.2% of participants reported *More Than One Race* as their racial category. Of the 156 intramural research protocols reporting data following the current 1997 OMB standards and designating an ethnicity in FY 2003, 92.8% identified a racial category and an ethnicity of not Hispanic. Whereas, 5.3% identified a racial category and an ethnic category of Hispanic/Latino and 1.9% of participants identified a racial category but did not report an ethnicity. (*Table 17*)

In FY 2004, approximately 1.9 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 951 intramural research protocols that continue to report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 10.5% and lowest for American Indian/Alaska Natives at 0.9%. Blacks (not-Hispanic) represented 5.6%, Hispanics 4%; and Whites (not Hispanic) 72% of the intramural research study population. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards and therefore, no data were reported in these categories. (*Table 19*)

For all intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2004, the largest racial minority group was Blacks at 9.14% and the smallest racial minority group was Hawaiian/Pacific Islanders at .01%. Asians represented 4.2%, American Indian/Alaska Natives 1.1% and Whites 78.7% of participants in all intramural clinical research. Approximately 0.2% of participants reported *More Than One Race* as their racial category. Of the 440 intramural research protocols following the current 1997 OMB standards designating an ethnicity in FY 2004, 95.7% identified a racial category and an ethnicity of not Hispanic. Whereas, 2.8% identified a racial category and an ethnic category of Hispanic/Latino and 1.5% of participants identified a racial category but did not report an ethnicity. (*Table 19*)

Table 1. Overview of NIH Extramural and Intramural Clinical Research: Number of Protocols and Enrollment by Sex, Reported In FY 2003

Protocols Reported**	Clinical Studies (Not NIH Defined Phase III)	NIH Defined Phase III Clinical Trials*	Total All Clinical Studies
Protocols with Enrollment	9,352	864	**10,216**
%	71.6%	88.4%	72.8%
Protocols with zero enrollment. Enrollment data has not yet been submitted	3,712	113	3,825
	28.4%	11.6%	27.2%
Total Number of Protocols	**13,064**	**977**	**14,041**
%	100.0%	100.0%	**100.0%**

Enrollment Reported	Clinical Studies (Not NIH Defined Phase III)	NIH Defined Phase III Clinical Trials	Total All Clinical Studies
Females Enrolled	8,220,593	293,888	8,514,481
%	57.7%	55.1%	57.6%
Males Enrolled	5,883,897	237,599	6,121,496
%	41.3%	44.5%	41.4%
Sex of Subjects is Unknown	134,285	1,992	136,277
%	0.9%	0.4%	0.9%
Total Subjects Enrolled	**14,238,775**	**533,479**	**14,772,254**
%	100.0%	100.0%	100.0%

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

Source: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, October 2001.

Table 2. Overview of NIH Extramural and Intramural Clinical Research: Number of Protocols and Enrollment by Sex, Reported In FY 2004

Protocols Reported	**Clinical Studies (Not NIH Defined Phase III)**	**NIH Defined Phase III Clinical Trials***	**Total All Clinical Studies**
Protocols with Enrollment	9,549	576	**10,125**
%	69.1%	83.2%	69.8%
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,271	116	4,387
	30.9%	16.8%	30.2%
Total Number of Protocols	**13,820**	**692**	**14,512**
%	100.0%	100.0%	**100.0%**

Enrollment Reported	**Clinical Studies (Not NIH Defined Phase III)**	**NIH Defined Phase III Clinical Trials**	**Total All Clinical Studies**
Females Enrolled	10,602,296	286,801	10,889,097
%	57.6%	55.5%	57.5%
Males Enrolled	7,513,411	228,481	7,741,892
%	40.8%	44.2%	40.9%
Sex of Subjects is Unknown	291,853	1,078	292,931
%	1.6%	0.2%	1.5%
Total Subjects Enrolled	**18,407,560**	**516,360**	**18,923,920**
%	100.0%	100.0%	100.0%

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

Source: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, October 2001.

Table 3. Overview of NIH Extramural and Intramural Clinical Research: Number of Sex Specific Protocols, and Domestic versus Foreign Protocols, Reported in FY2003

Protocols Tracked		Clinical Studies (Not NIH Defined Phase III)	NIH Defined Phase III Clinical Trials*	Total All Clinical Studies
Protocols reporting women only		1,215	189	1,404
%		9.3%	19.3%	10.0%
Protocols reporting men only		530	84	614
%		4.1%	8.6%	4.4%
Other Protocols with Enrollment (excluding women only and men only protocols)		7,607	591	8,198
%		58.2%	60.5%	58.4%
Protocols with zero enrollment. Enrollment data has not yet been submitted.		3,712	113	3,825
%		28.4%	11.6%	27.2%
Total Number of Protocols		**13,064**	**977**	**14,041**
%		100.0%	100.0%	100.0%

Domestic and Foreign Protocols Tracked				
Domestic Protocols with Enrollment		**8,922**	**656**	**9,578**
%		68.3%	67.1%	68.2%
Domestic Protocols with Zero Enrollment		**3,532**	**106**	**3,638**
%		27.0%	10.8%	25.9%
Subtotal: Total Domestic Protocols		**12,454**	**762**	**13,216**
%		95.3%	78.0%	94.1%
Foreign Protocols with Enrollment		**430**	**208**	**638**
%		3.3%	21.3%	4.5%
Foreign Protocols with Zero Enrollment.		**180**	**7**	**187**
%		1.4%	0.7%	1.3%
Subtotal: Total Foreign Protocols		**610**	**215**	**825**
%		4.7%	22.0%	5.9%
Total Number of All Protocols Tracked**		**13,064**	**977**	**14,041**
%		100.0%	100.0%	100.0%

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

Source: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, October 2001.

* *Enrollment for Domestic and Foreign sites are reported as separate protocols. Totals are not corrected for 37studies that have both Domestic and Foreign enrollment sites/protocols.

Table 4. Overview of NIH Extramural and Intramural Clinical Research: Number of Sex Specific Protocols, and Domestic versus Foreign Protocols, Reported in FY2004

Protocols Tracked		**Clinical Studies (Not NIH Defined Phase III)**	**NIH Defined Phase III Clinical Trials***	**Total All Clinical Studies**
Protocols reporting women only		1,323	147	1,470
%		9.6%	21.2%	10.1%
Protocols reporting men only		477	34	511
%		3.5%	4.9%	3.5%
Other Protocols with Enrollment (excluding women only and men only protocols)		7,749	395	8,144
%		56.1%	57.1%	56.1%
Protocols with zero enrollment. Enrollment data has not yet been submitted.		4,271	116	4,387
%		30.9%	16.8%	30.2%
Total Number of Protocols		**13,820**	**692**	**14,512**
%		100.0%	100.0%	100.0%

Domestic and Foreign Protocols Tracked				
Domestic Protocols with Enrollment		**9,207**	**553**	**9,760**
%		66.6%	79.9%	67.3%
Domestic Protocols with Zero Enrollment		**4,090**	**102**	**4,192**
%		29.6%	14.7%	28.9%
Subtotal: Total Domestic Protocols		**13,297**	**655**	**13,952**
%		96.2%	94.7%	96.1%
Foreign Protocols with Enrollment		**342**	**23**	**365**
%		2.5%	3.3%	2.5%
Foreign Protocols with Zero Enrollment.		**181**	**14**	**195**
%		1.3%	2.0%	1.3%
Subtotal: Total Foreign Protocols		**523**	**37**	**560**
%		3.8%	5.3%	3.9%
Total Number of All Protocols Tracked**		**13,820**	**692**	**14,512**
%		100.0%	100.0%	100.0%

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

Source: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, October 2001.

* *Enrollment for Domestic and Foreign sites are reported as separate protocols. Totals are not corrected for 55 studies that have both Domestic and Foreign enrollment sites/protocols.

Table 5. Overview of NIH Extramural and Intramural Clinical Research: Enrollment by Sex, and Domestic versus Foreign Enrollment, Reported in FY 2003

Enrollment Reported		**Clinical Studies (Not NIH Defined Phase III)**	**NIH Defined Phase III Clinical Trials***	**Total All Clinical Studies**
Protocols reporting women only		2,881,338	163,220	3,044,558
%		20.2%	30.6%	20.6%
Protocols reporting men only		280,002	71,985	351,987
%		2.0%	13.5%	2.4%
Protocols excluding female-only and men-only enrollment protocols		11,077,435	298,274	11,375,709
%		77.8%	55.9%	77.0%
Protocols with zero enrollment. Enrollment data has not yet been submitted.		0	0	0
%		0.0%	0.0%	0.0%
Enrollment Totals for all studies		**14,238,775**	**533,479**	**14,772,254**
%		100.0%	100.0%	100.0%

Enrollment Reported by Domestic or Foreign Site				
Domestic Enrollment		11,427,288	484,069	11,911,357
%		80.3%	90.7%	80.6%
Foreign Enrollment		2,811,487	49,410	2,860,897
%		19.7%	9.3%	19.4%
Enrollment Totals for All Studies		**14,238,775**	**533,479**	**14,772,254**
%		100.0%	100.0%	100.0%

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

Source: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, October 2001.

Table 6. Overview of NIH Extramural and Intramural Clinical Research: Enrollment by Sex, and Domestic versus Foreign Enrollment, Reported in FY 2004

Enrollment Reported		**Clinical Studies (Not NIH Defined Phase III)**	**NIH Defined Phase III Clinical Trials***	**Total All Clinical Studies**
Protocols reporting women only		3,096,486	160,148	3,256,634
%		16.8%	31.0%	17.2%
Protocols reporting men only		172,720	72,762	245,482
%		0.9%	14.1%	1.3%
Protocols excluding female-only and men-only enrollment protocols		15,138,354	283,450	15,421,804
%		82.2%	54.9%	81.5%
Protocols with zero enrollment. Enrollment data has not yet been submitted.		0	0	0
%		0.0%	0.0%	0.0%
Enrollment Totals for all studies		**18,407,560**	**516,360**	**18,923,920**
%		100.0%	100.0%	100.0%

Enrollment Reported by Domestic or Foreign Site				
Domestic Enrollment		13,892,559	467,234	14,359,793
%		75.5%	90.5%	75.9%
Foreign Enrollment		4,515,001	49,126	4,564,127
%		24.5%	9.5%	24.1%
Enrollment Totals for All Studies		**18,407,560**	**516,360**	**18,923,920**
%		100.0%	100.0%	100.0%

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

Source: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, October 2001.

Table 7. Summary of NIH Extramural and Intramural Clinical Research Enrollment by Race and Ethnicity, Reported in FY 2003 and FY 2004

The shaded portions of the Tables below show the race/ethnicity categories that were identified as minority categories in this question. The Minority Totals are also shaded.

These data are obtained from the NIH population tracking data system for clinical research studies. Investigators report enrollment data using either the "Old Form" or the "New Form" New studies are using only the "New Form"; therefore, the totals on the "Old Form" are declining over time while the totals on the "New Form" are increasing.

NOTE 1: The data from the Old Form (1977 OMB Standards, combined race/ethnicity format) and the New Form (1997 OMB Standards, separate race and ethnicity formats) cannot be accurately combined for a specific category; e.g., in 1997, "Asian" is a separate race than "Hawaiian/Pacific Islander"; and "Hispanic or Latino" in the New form is reported also by racial category and included in the appropriate columns under "Total of All Subjects by Race".

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format

FY Funded	FY Reported	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other	Total	Minority Total
2002	2003	36,579	730,542	472,426	288,523	3,238,284	278,901	5,045,255	**1,528,070**
	%	0.73%	14.48%	9.36%	5.72%	64.18%	5.53%	100.00%	**30.29%**
2003	2004	29,387	307,052	342,188	214,322	2,348,529	172,130	3,413,608	**892,949**
	%	0.86%	8.99%	10.02%	6.28%	68.80%	5.04%	100.00%	**26.16%**

New Form: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats

		Total of All Subjects by Race									Total of All Subjects by Ethnicity			
FY Funded	FY Reported	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Minority Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
2002	2003	63,544	2,138,002	960,090	37,569	5,415,710	99,462	1,012,622	*9,726,999*	**3,199,205**	8,162,259	611,641	953,099	*9,726,999*
	%	0.65%	21.98%	9.87%	0.39%	55.68%	1.02%	10.41%	*100.00%*	**32.89%**	83.91%	6.29%	9.80%	*100.00%*
2003	2004	98,047	4,345,396	1,379,857	54,452	8,065,069	186,241	1,381,250	*15,510,312*	**5,877,752**	13,168,842	756,339	1,585,131	*15,510,312*
	%	0.63%	28.02%	8.90%	0.35%	52.00%	1.20%	8.91%	*100.00%*	**37.90%**	84.90%	4.88%	10.22%	*100.00%*

NOTE 2: Summary Totals are provided for two years for the Old Form and the New Form. The Summary Minority Total Estimate (the sum of Old and New Forms) is only an estimate of the total Minority enrollment.

Summary Totals: Old + New Forms

FY Funded	FY Reported	Total	Summary Minority Total Estimate
2002	2003	**14,772,254**	**4,727,275**
	%	**100%**	**32.00%**
2003	2004	**18,923,920**	**6,770,701**
	%	**100%**	**35.78%**

Table 8. Summary of NIH Extramural and Intramural Phase III Clinical Research Enrollment by Race and Ethnicity, Reported in FY 2003 and FY 2004

NOTE: Table 5 includes ONLY NIH Defined Phase III Clinical Trials, which are a subset of all clinical trials. In May 2005, applicants using the PHS 398 will be required to identify when their proposed study is a clinical trial.

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format

FY Funded	FY Reported	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/ Other	Total	Minority Total
2002	2003	1,703	20,050	50,186	29,402	338,269	16,666	456,276	**101,341**
	%	0.37%	4.39%	11.00%	6.44%	74.14%	3.65%	100.00%	**22.21%**
2003	2004	1,439	18,574	43,953	32,085	257,894	13,864	367,809	**96,051**
	%	0.39%	5.05%	11.95%	8.72%	70.12%	3.77%	100.00%	**26.11%**

New Form: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats

		Total of All Subjects by Race									Total of All Subjects by Ethnicity			
FY Funded	FY Reported	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown /Other	Total	Minority Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
2002	2003	407	2,096	21,892	116	44,086	804	7,802	*77,203*	**24,511**	59,882	7,486	9,835	*77,203*
	%	0.53%	2.71%	28.36%	0.15%	57.10%	1.04%	10.11%	*100.00%*	**31.75%**	77.56%	9.70%	12.74%	*100.00%*
2003	2004	1,219	3,647	36,136	442	98,703	3,839	4,565	*148,551*	**41,444**	128,370	12,650	7,531	*148,551*
	%	0.82%	2.46%	24.33%	0.30%	66.44%	2.58%	3.07%	*100.00%*	**27.90%**	86.41%	8.52%	5.07%	*100.00%*

NOTE 2: Summary Totals are provided for two years for the Old Form and the New Form. The Summary Minority Total Estimate (the sum of Old and New Forms) is only an estimate of the total minority enrollment.

SUMMARY TOTALS: Old Form + New Form

FY Funded	FY Reported	Total, Old + New Form		Summary Minority Total Estimate- Old Form + New Form
2002	2003	533,479		125,852
	%	100%		24%
2003	2004	516,360		137,495
	%	100%		27%

Table 9. Aggregate Enrollment Data for All Extramural Research Protocols Reported in FY 2003: Percent Analysis

Number of Protocols with Enrollment Data:	3,704

Legend

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

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

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

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	8,964	287,709	230,397	142,009	1,159,679	81,692	1,910,450
	0.28%	**8.95%**	**7.17%**	**4.42%**	**36.08%**	**2.54%**	**59.44%**
	0.47%	*15.06%*	*12.06%*	*7.43%*	*60.70%*	*4.28%*	*100.00%*
	49.33%	53.44%	62.43%	61.70%	60.77%	54.38%	59.44%
Male	7,149	243,553	136,148	86,874	741,621	56,695	1,272,040
	0.22%	**7.58%**	**4.24%**	**2.70%**	**23.07%**	**1.76%**	**39.57%**
	0.56%	*19.15%*	*10.70%*	*6.83%*	*58.30%*	*4.46%*	*100.00%*
	39.34%	45.24%	36.89%	37.74%	38.86%	37.74%	39.57%
Unknown	2,059	7,080	2,510	1,294	7,017	11,838	31,798
	0.064%	**0.22%**	**0.08%**	**0.04%**	**0.22%**	**0.37%**	**0.99%**
	6.48%	*22.27%*	*7.89%*	*4.07%*	*22.07%*	*37.23%*	*100.00%*
	11.33%	1.32%	0.68%	0.56%	0.37%	7.88%	0.99%
Total	18,172	538,342	369,055	230,177	1,908,317	150,225	3,214,288
	0.57%	**16.75%**	**11.48%**	**7.16%**	**59.37%**	**4.67%**	**100.00%**
	0.57%	*16.75%*	*11.48%*	*7.16%*	*59.37%*	*4.67%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	5,157

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	42,920	769,183	602,381	16,157	3,503,244	55,687	744,429	5,734,001	4,652,012	378,509	703,480	5,734,001
	0.44%	**7.91%**	**6.19%**	**0.17%**	**36.03%**	**0.57%**	**7.66%**	**58.97%**	**47.84%**	**3.89%**	**7.23%**	**58.97%**
	0.75%	*13.41%*	*10.51%*	*0.28%*	*61.10%*	*0.97%*	*12.98%*	*100.00%*	*81.13%*	*6.60%*	*12.27%*	*100.00%*
	67.56%	35.98%	62.78%	43.01%	64.71%	55.99%	73.53%	58.97%	57.01%	61.90%	73.81%	58.97%
Male	19,229	1,366,927	349,343	15,638	1,895,347	43,321	210,903	3,900,708	3,486,972	230,768	182,968	3,900,708
	0.20%	**14.06%**	**3.59%**	**0.16%**	**19.49%**	**0.45%**	**2.17%**	**40.11%**	**35.86%**	**2.37%**	**1.88%**	**40.11%**
	0.49%	*35.04%*	*8.96%*	*0.40%*	*48.59%*	*1.11%*	5.41%	*100.00%*	*89.39%*	*5.92%*	*4.69%*	*100.00%*
	30.27%	63.94%	36.41%	41.63%	35.01%	43.56%	20.83%	40.11%	42.74%	37.74%	19.20%	40.11%
Unknown	1,383	1,712	7,829	5,773	14,934	448	57,114	89,193	20,400	2,201	66,592	89,193
	0.01%	**0.02%**	**0.08%**	**0.06%**	**0.15%**	**0.00%**	*0.59%*	**0.92%**	**0.21%**	**0.02%**	**0.68%**	**0.92%**
	1.55%	*1.92%*	*8.78%*	6.47%	*16.74%*	*0.50%*	*64.03%*	*100.00%*	*22.87%*	*2.47%*	*74.66%*	*100.00%*
	2.18%	0.08%	0.82%	15.37%	0.28%	0.45%	5.64%	0.92%	0.25%	0.36%	6.99%	0.92%
Total	63,532	2,137,822	959,553	37,568	5,413,525	99,456	1,012,446	9,723,902	8,159,384	611,478	953,040	9,723,902
	0.65%	**21.99%**	**9.87%**	**0.39%**	**55.67%**	**1.02%**	**10.41%**	**100.00%**	**83.91%**	**6.29%**	**9.80%**	**100.00%**
	0.65%	*21.99%*	*9.87%*	*0.39%*	*55.67%*	*1.02%*	*10.41%*	*100.00%*	*83.91%*	*6.29%*	*9.80%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	7,644,451	Males	5,172,748	Unknown	120,991	Total	12,938,190
	59.08%		39.98%		0.94%		100%

Total Number of Protocols with Enrollment Data:	8,861

Table 9: Aggregate Enrollment Data for All Extramural Research Protocols Reported in FY2003

Data Table Comments:

More females (7,644,451 or 59.1%) than males (5,172,748 or 39.9%) are enrolled in aggregate extramural research protocols.

Largest identified racial group is White at 59.37% following the 1977 OMB standards and 55.67% following the 1997 OMB standards.

Largest identified racial minority group is Asian at 16.75% following the 1977 OMB standards and 21.9% following the 1997 OMB

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native at (0.6%).

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

6.3% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 7.2% of participants identified as Hispanic according to the 1977 OMB standards.

Table 10: Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2003

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

Number of Protocols with Enrollment Data: 2,901

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	7,541	251,238	153,109	91,828	650,776	70,595	1,225,087
	0.32%	**10.64%**	**6.48%**	**3.89%**	**27.55%**	**2.99%**	**51.87%**
	0.62%	*20.51%*	*12.50%*	*7.50%*	*53.12%*	*5.76%*	*100.00%*
	45.67%	50.63%	54.62%	52.10%	51.06%	59.82%	51.87%
Male	6,911	237,929	124,693	83,146	616,728	35,579	1,104,986
	0.29%	**10.07%**	**5.28%**	**3.52%**	**26.11%**	**1.51%**	**46.78%**
	0.63%	*21.53%*	*11.28%*	*7.52%*	*55.81%*	*3.22%*	*100.00%*
	41.86%	47.96%	44.48%	47.17%	48.39%	30.15%	46.78%
Unknown	2,059	7,080	2,510	1,294	7,017	11,838	31,798
	0.087%	**0.30%**	**0.11%**	**0.05%**	**0.30%**	**0.50%**	**1.35%**
	6.48%	*22.27%*	*7.89%*	*4.07%*	*22.07%*	*37.23%*	*100.00%*
	12.47%	1.43%	0.90%	0.73%	0.55%	10.03%	1.35%
Total	16,511	496,247	280,312	176,268	1,274,521	118,012	2,361,871
	0.70%	**21.01%**	**11.87%**	**7.46%**	**53.96%**	**5.00%**	**100.00%**
	0.70%	*21.01%*	*11.87%*	*7.46%*	*53.96%*	*5.00%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend
Bold: Percentage of Total No. of Participants in Research Protocols (Old or New Form)
Italics: Percentage of Total No. of Participants Sorted by Sex/Gender (Row Total)
Typeface: Percentage of Total No. of Participants Sorted by Race/Ethnicity (Column Total

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 4,161

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	Not Hispanic	Hispanic or Latino	Unknown/Not Reported	Total
Female	19,882	712,983	401,586	14,828	2,146,846	45,306	248,738	3,590,169	3,126,733	243,467	219,969	3,590,169
	0.27%	**9.59%**	**5.40%**	**0.20%**	**28.86%**	**0.61%**	**3.34%**	**48.26%**	**42.03%**	**3.27%**	**2.96%**	**48.26%**
	0.55%	*19.86%*	*11.19%*	*0.41%*	*59.80%*	*1.26%*	*6.93%*	*100.00%*	*87.09%*	*6.78%*	*6.13%*	*100.00%*
	49.45%	34.84%	53.88%	41.00%	54.00%	51.89%	49.02%	48.26%	48.05%	51.89%	47.66%	48.26%
Male	18,938	1,331,988	335,965	15,569	1,813,589	41,563	201,540	3,759,152	3,360,703	223,511	174,938	3,759,152
	0.25%	**17.91%**	**4.52%**	**0.21%**	**24.38%**	**0.56%**	**2.71%**	**50.54%**	**45.18%**	**3.00%**	**2.35%**	**50.54%**
	0.50%	*35.43%*	*8.94%*	*0.41%*	*48.24%*	*1.11%*	**5.36%**	*100.00%*	*89.40%*	*5.95%*	*4.65%*	*100.00%*
	47.11%	65.08%	45.07%	43.04%	45.62%	47.60%	39.72%	50.54%	51.64%	47.64%	37.91%	50.54%
Unknown	1,383	1,712	7,829	5,773	14,934	448	57,114	89,193	20,400	2,201	66,592	89,193
	0.02%	**0.02%**	**0.11%**	**0.08%**	**0.20%**	**0.01%**	*0.77%*	**1.20%**	**0.27%**	**0.03%**	**0.90%**	**1.20%**
	1.55%	*1.92%*	*8.78%*	**6.47%**	*16.74%*	*0.50%*	*64.03%*	*100.00%*	*22.87%*	*2.47%*	*74.66%*	*100.00%*
	3.44%	0.08%	1.05%	15.96%	0.38%	0.51%	11.26%	1.20%	0.31%	0.47%	14.43%	1.20%
Total	40,203	2,046,683	745,380	36,170	3,975,369	87,317	507,392	7,438,514	6,507,836	469,179	461,499	7,438,514
	0.54%	***27.51%***	***10.02%***	***0.49%***	***53.44%***	***1.17%***	***6.82%***	***100.00%***	***87.49%***	***6.31%***	***6.20%***	***100.00%***
	0.54%	*27.51%*	*10.02%*	*0.49%*	*53.44%*	*1.17%*	*6.82%*	*100.00%*	*87.49%*	*6.31%*	*6.20%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

TOTAL		TOTAL		TOTAL		OVERALL	
Females	4,815,256	Males	4,864,138	Unknown	120,991	Total	9,800,385
	49.13%		49.63%		1.23%		100%

Total Number of Protocols with Enrollment Data: 7,062

Table 10: Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2003

Data Table Comments:

There were 8,861 protocols of which 1,280 were *female-only* protocols and 519 were *male-only* protocols.

Excluding sex-specific studies, the number of females (4,815,256 or 49.1%) to males (4,864,138 or 49.6%) enrolled in extramural research protocols are closely representative of the general population.

Largest identified racial group is White at 53.9% following the 1977 OMB standards and 53.4% following the 1997 OMB standards.

Largest identified racial minority group is Asian/Pacific Islanders at 21% following the 1977 OMB standards and 27.5% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.7%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.49%).

6.3% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards, whereas 7.5% of participants identified as Hispanic according to 1977 OMB standards.

Table 11. Aggregate Enrollment Data for All Extramural Research Protocols Reported in FY 2004: Percent Analysis

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	6,366	68,746	151,718	85,891	615,764	22,920	951,405
	0.42%	**4.49%**	**9.91%**	**5.61%**	**40.23%**	**1.50%**	**62.16%**
	0.67%	*7.23%*	*15.95%*	*9.03%*	*64.72%*	*2.41%*	*100.00%*
	58.76%	62.51%	64.13%	61.72%	62.08%	54.39%	62.16%
Male	4,391	40,875	81,883	52,154	373,856	14,787	567,946
	0.29%	**2.67%**	**5.35%**	**3.41%**	**24.43%**	**0.97%**	**37.11%**
	0.77%	*7.20%*	*14.42%*	*9.18%*	*65.83%*	*2.60%*	*100.00%*
	40.53%	37.17%	34.61%	37.48%	37.69%	35.09%	37.11%
Unknown	76	353	2,979	1,119	2,305	4,434	11,266
	0.005%	**0.02%**	**0.19%**	**0.07%**	**0.15%**	**0.29%**	**0.74%**
	0.67%	*3.13%*	*26.44%*	*9.93%*	*20.46%*	*39.36%*	*100.00%*
	0.70%	0.32%	1.26%	0.80%	0.23%	10.52%	0.74%
Total	10,833	109,974	236,580	139,164	991,925	42,141	1,530,617
	0.71%	**7.19%**	**15.46%**	**9.09%**	**64.81%**	**2.75%**	**100.00%**
	0.71%	*7.18%*	*15.46%*	*9.09%*	*64.81%*	*2.75%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:	1,831

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	6,903

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	66,063	1,915,721	840,059	28,339	5,044,861	103,608	995,925	8,994,576	7,390,050	472,368	1,132,158	8,994,576
	0.43%	**12.40%**	**5.44%**	**0.18%**	**32.66%**	**0.67%**	**6.45%**	**58.23%**	**47.84%**	**3.06%**	**7.33%**	**58.23%**
	0.73%	*21.30%*	*9.34%*	*0.32%*	*56.09%*	*1.15%*	*11.07%*	*100.00%*	*82.16%*	*5.25%*	*12.59%*	*100.00%*
	67.87%	44.11%	61.14%	52.05%	62.95%	55.67%	72.33%	58.23%	56.38%	62.60%	71.47%	58.23%
Male	29,706	2,415,164	517,220	23,839	2,820,402	81,024	299,627	6,186,982	5,535,928	275,989	375,065	6,186,982
	0.19%	**15.64%**	**3.35%**	**0.15%**	**18.26%**	**0.52%**	**1.94%**	**40.06%**	**35.84%**	**1.79%**	**2.43%**	**40.06%**
	0.48%	*39.04%*	*8.36%*	*0.39%*	*45.59%*	*1.31%*	**4.84%**	*100.00%*	*89.48%*	*4.46%*	*6.06%*	*100.00%*
	30.52%	55.61%	37.64%	43.78%	35.19%	43.54%	21.76%	40.06%	42.24%	36.58%	23.68%	40.06%
Unknown	1,564	11,843	16,711	2,270	149,289	1,479	81,397	264,553	181,424	6,168	76,961	264,553
	0.01%	**0.08%**	**0.11%**	**0.01%**	**0.97%**	**0.01%**	*0.53%*	**1.71%**	**1.17%**	**0.04%**	**0.50%**	**1.71%**
	0.59%	*4.48%*	6.32%	*0.86%*	*56.43%*	*0.56%*	*30.77%*	*100.00%*	*68.58%*	*2.33%*	*29.09%*	*100.00%*
	1.61%	0.27%	1.22%	4.17%	1.86%	0.79%	5.91%	1.71%	1.38%	0.82%	4.86%	1.71%
Total	97,333	4,342,728	1,373,990	54,448	8,014,552	186,111	1,376,949	15,446,111	13,107,402	754,525	1,584,184	15,446,111
	0.63%	**28.12%**	**8.90%**	**0.35%**	**51.89%**	**1.20%**	**8.91%**	**100.00%**	**84.86%**	**4.88%**	**10.26%**	**100.00%**
	0.63%	*28.12%*	*8.90%*	*0.35%*	*51.89%*	*1.20%*	*8.91%*	*100.00%*	*84.86%*	*4.88%*	*10.26%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	9,945,981	Males	6,754,928	Unknown	275,819	Total	16,976,728
	58.59%		39.79%		1.62%		100%

Total Number of Protocols with Enrollment Data:	8,734

Table 11: Aggregate Enrollment Data for All Extramural Research Protocols Reported in FY2004: Percentage Analysis

Data Table Comments:

More females (9,945,981 or 58.6%) than males (6,754,928 or 39.8%) are enrolled in aggregate extramural research protocols.

Largest identified racial group is Whites at 64.8% following the 1977 OMB standards and 52% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 15.46% following the 1977 OMB standards.

Largest identified racial minority group is Asians at 28.1% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.7%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.35%).

4.8% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards, whereas 9% of participants identified as Hispanic according to 1977 OMB standards.

Table 12: Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2004: Percent Analysis

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

Number of Protocols with Enrollment Data: 1,490

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	5,107	45,875	94,686	57,592	325,993	17,185	546,438
	0.49%	**4.38%**	**9.04%**	**5.50%**	**31.13%**	**1.64%**	**52.17%**
	0.93%	*8.40%*	*17.33%*	*10.54%*	*59.66%*	*3.14%*	*100.00%*
	54.64%	54.35%	56.56%	53.51%	50.70%	48.36%	52.17%
Male	4,163	38,172	69,755	48,924	314,694	13,914	489,622
	0.40%	**3.64%**	**6.66%**	**4.67%**	**30.05%**	**1.33%**	**46.75%**
	0.85%	*7.80%*	*14.25%*	*9.99%*	*64.27%*	*2.84%*	*100.00%*
	44.54%	45.23%	41.66%	45.45%	48.94%	39.16%	46.75%
Unknown	76	353	2,979	1,119	2,305	4,434	11,266
	0.007%	**0.03%**	**0.28%**	**0.11%**	**0.22%**	**0.42%**	**1.08%**
	0.67%	*3.13%*	*26.44%*	*9.93%*	*20.46%*	*39.36%*	*100.00%*
	0.81%	0.42%	1.78%	1.04%	0.36%	12.48%	1.08%
Total	9,346	84,400	167,420	107,635	642,992	35,533	1,047,326
	0.89%	**8.06%**	**15.99%**	**10.28%**	**61.39%**	**3.39%**	**100.00%**
	0.89%	*8.06%*	*15.99%*	*10.28%*	*61.39%*	*3.39%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 5,482

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	32,092	1,755,601	659,165	25,711	3,478,447	88,580	362,622	6,402,218	5,632,779	288,516	480,923	6,402,218
	0.25%	**13.78%**	**5.18%**	**0.20%**	**27.31%**	**0.70%**	**2.85%**	**50.26%**	**44.22%**	**2.27%**	**3.78%**	**50.26%**
	0.50%	*27.42%*	*10.30%*	*0.40%*	*54.33%*	*1.38%*	*5.66%*	*100.00%*	*87.98%*	*4.51%*	*7.51%*	*100.00%*
	50.83%	42.46%	56.01%	49.81%	54.34%	52.21%	48.99%	50.26%	50.10%	51.04%	51.78%	50.26%
Male	29,476	2,366,994	500,980	23,636	2,773,778	79,603	296,238	6,070,705	5,429,380	270,603	370,922	6,070,905
	0.23%	**18.58%**	**3.93%**	**0.19%**	**21.78%**	**0.62%**	**2.33%**	**47.66%**	**42.62%**	**2.12%**	**2.91%**	**47.66%**
	0.49%	*38.99%*	*8.25%*	*0.39%*	*45.69%*	*1.31%*	**4.88%**	*100.00%*	*89.43%*	*4.46%*	*6.11%*	*100.00%*
	46.69%	57.25%	42.57%	45.79%	43.33%	46.92%	40.02%	47.66%	48.29%	47.87%	39.94%	47.66%
Unknown	1,564	11,843	16,711	2,270	149,289	1,479	81,397	264,553	181,424	6,168	76,961	264,553
	0.01%	**0.09%**	**0.13%**	**0.02%**	**1.17%**	**0.01%**	*0.64%*	**2.08%**	**1.42%**	**0.05%**	**0.60%**	**2.08%**
	0.59%	*4.48%*	6.32%	*0.86%*	*56.43%*	*0.56%*	*30.77%*	*100.00%*	*68.58%*	*2.33%*	*29.09%*	*100.00%*
	2.48%	0.29%	1.42%	4.40%	2.33%	0.87%	11.00%	2.08%	1.61%	1.09%	8.29%	2.08%
Total	63,132	4,134,438	1,176,856	51,617	6,401,514	169,662	740,257	12,737,476	11,243,583	565,287	928,806	12,737,676
	0.50%	**32.46%**	**9.24%**	**0.41%**	**50.26%**	**1.33%**	**5.81%**	**100.00%**	**88.27%**	**4.44%**	**7.29%**	**100.00%**
	0.50%	32.46%	9.24%	0.41%	50.26%	1.33%	5.81%	100.00%	88.27%	4.44%	7.29%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	6,948,656	Males	6,560,527	Unknown	275,819	Total	13,785,002
	50.41%		47.59%		2.00%		100%

Total Number of Protocols with Enrollment Data: 6,972

Table 12: Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2004

Data Table Comments:

There were 8,734 protocols of which 1,336 were *female-only* protocols and 86 were *male-only* protocols.

Excluding sex-specific studies, the number of females (6,948,656 or 50.4%) to males (6,560,527 or 47.6%) enrolled in intramural research protocols are closely representative of the general population.

Largest identified racial group is White at 61.4% following the 1977 OMB standards and 50.3% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 16% following the 1977 OMB standards.

Largest identified racial minority group is Asians at 32.5% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.9%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.41%).

4.4% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards, whereas 10.3% of participants identified as Hispanic according to 1977 OMB standards.

Table 13. Aggregate Enrollment Data for Extramural Phase III Research Protocols Reported in FY 2003: Percent Analysis

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

Number of Protocols
with Enrollment Data: 635

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	1,038	4,744	29,109	16,302	190,387	4,565	246,145
	0.24%	**1.10%**	**6.76%**	**3.79%**	**44.22%**	**1.06%**	**57.18%**
	0.42%	*1.93%*	*11.83%*	*6.62%*	*77.35%*	*1.85%*	*100.00%*
	61.42%	60.08%	58.53%	55.92%	57.31%	46.39%	57.18%
Male	652	3,152	20,621	12,767	141,793	4,358	183,343
	0.15%	**0.73%**	**4.79%**	**2.97%**	**32.94%**	**1.01%**	**42.59%**
	0.36%	*1.72%*	*11.25%*	*6.96%*	*77.34%*	*2.38%*	*100.00%*
	38.58%	39.92%	41.47%	43.79%	42.68%	44.28%	42.59%
Unknown	0	0	1	84	20	918	1,023
	0.000%	**0.00%**	**0.00%**	**0.02%**	**0.00%**	**0.21%**	**0.24%**
	0.00%	*0.00%*	*0.10%*	*8.21%*	*1.96%*	*89.74%*	*100.00%*
	0.00%	0.00%	0.00%	0.29%	0.01%	9.33%	0.24%
Total	1,690	7,896	49,731	29,153	332,200	9,841	430,511
	0.39%	**1.83%**	**11.66%**	**6.77%**	**77.16%**	**2.29%**	**100.00%**
	0.39%	*1.83%*	*11.55%*	*6.77%*	*77.16%*	*2.29%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols
with Enrollment Data: 196

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	164	964	12,546	47	18,355	454	2,624	35,154	26,928	2,739	5,487	35,154
	0.21%	**1.25%**	**16.30%**	**0.06%**	**23.85%**	**0.59%**	**3.41%**	**45.69%**	**35.00%**	**3.56%**	**7.13%**	**45.69%**
	0.47%	*2.74%*	*35.69%*	*0.13%*	*52.21%*	*1.29%*	*7.46%*	*100.00%*	*76.60%*	*7.79%*	*15.61%*	*100.00%*
	40.29%	46.15%	57.54%	40.87%	41.77%	56.54%	33.70%	45.69%	45.15%	36.65%	55.82%	45.69%
Male	243	1,123	9,247	68	25,545	348	4,252	40,826	32,662	4,731	3,433	40,826
	0.32%	**1.46%**	**12.02%**	**0.09%**	**33.20%**	**0.45%**	**5.53%**	**53.06%**	**42.45%**	**6.15%**	**4.46%**	**53.06%**
	0.60%	*2.75%*	*22.65%*	*0.17%*	*62.57%*	*0.85%*	10.41%	*100.00%*	*80.00%*	*11.59%*	*8.41%*	*100.00%*
	59.71%	53.76%	42.41%	59.13%	58.13%	43.34%	54.61%	53.06%	54.76%	63.30%	34.92%	53.06%
Unknown	0	2	10	0	45	1	910	968	54	4	910	968
	0.00%	**0.00%**	**0.01%**	**0.00%**	**0.06%**	**0.00%**	*1.18%*	**1.26%**	**0.07%**	**0.01%**	**1.18%**	**1.26%**
	0.00%	*0.21%*	*1.03%*	0.00%	*4.65%*	*0.10%*	*94.01%*	*100.00%*	*5.58%*	*0.41%*	*94.01%*	*100.00%*
	0.00%	0.10%	0.05%	0.00%	0.10%	0.12%	11.69%	1.26%	0.09%	0.05%	9.26%	1.26%
Total	407	2,089	21,803	115	43,945	803	7,786	76,948	59,644	7,474	9,830	76,948
	0.53%	**2.71%**	**28.33%**	**0.15%**	**57.11%**	**1.04%**	**10.12%**	**100.00%**	**77.51%**	**9.71%**	**12.77%**	**100.00%**
	0.53%	*2.71%*	*28.33%*	*0.15%*	*57.11%*	*1.04%*	*10.12%*	*100.00%*	*77.51%*	*9.71%*	*12.77%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form

TOTAL		TOTAL		TOTAL		OVERALL	
Females	281,299	Males	224,169	Unknown	1,991	Total	507,459
	55.43%		44.17%		0.39%		100%

Total Number of Protocols with Enrollment Data: 831

Table 13: Aggregate Enrollment Data for Extramural Phase III Research Protocols Reported in FY2003: Percent Analysis

Data Table Comments:

Substantial numbers of women and minorities are enrolled in Phase III research protocols reported in FY2003.

More females (281,299 or 55.4%) than males (224,169 or 44.2%) are enrolled in aggregate extramural research protocols.

Largest identified racial group is Whites at 77.2% following the 1977 OMB standards and 57.1% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 11.6% following the 1977 OMB standards and 28.3% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.4%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.20%).

10% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 6.7% of participants identified as Hispanic according to the 1977 OMB standards.

Table 14: Aggregate Enrollment Data for Extramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Reported in FY2003: Percent Analysis

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

Number of Protocols with Enrollment Data: 413

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total
Female	476	1,487	15,509	10,778	60,941	2,129	91,320
	0.23%	**0.71%**	**7.40%**	**5.14%**	**29.09%**	**1.02%**	**43.59%**
	0.52%	*1.63%*	*16.98%*	*11.80%*	*66.73%*	*2.33%*	*100.00%*
	49.28%	43.97%	50.36%	50.31%	41.46%	35.75%	43.59%
Male	490	1,895	15,285	10,561	86,028	2,909	117,168
	0.23%	**0.90%**	**7.30%**	**5.04%**	**41.06%**	**1.39%**	**55.92%**
	0.42%	*1.62%*	*13.05%*	*9.01%*	*73.42%*	*2.48%*	*100.00%*
	50.72%	56.03%	49.63%	49.30%	58.53%	48.84%	55.92%
Unknown	0	0	1	84	20	918	1,023
	0.000%	**0.00%**	**0.00%**	**0.04%**	**0.01%**	**0.44%**	**0.49%**
	0.00%	*0.00%*	*0.10%*	*8.21%*	*1.96%*	*89.74%*	*100.00%*
	0.00%	0.00%	0.00%	0.39%	0.01%	15.41%	0.49%
Total	966	3,382	30,795	21,423	146,989	5,956	209,511
	0.46%	**1.61%**	**14.70%**	**10.23%**	**70.16%**	**2.84%**	**100.00%**
	0.46%	*1.61%*	*14.70%*	*10.23%*	*70.16%*	*2.84%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 148

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	93	840	8,679	40	14,645	207	2,258	26,762	19,192	2,192	5,378	26,762
	0.15%	**1.34%**	**13.82%**	**0.06%**	**23.33%**	**0.33%**	**3.60%**	**42.63%**	**30.57%**	**3.49%**	**8.57%**	**42.63%**
	0.35%	*3.14%*	*32.43%*	*0.15%*	*54.72%*	*0.77%*	*8.44%*	*100.00%*	*71.71%*	*8.19%*	*20.10%*	*100.00%*
	32.29%	46.93%	50.13%	37.04%	40.65%	49.64%	33.03%	42.63%	40.88%	35.78%	55.40%	42.63%
Male	195	948	8,623	68	21,337	209	3,669	35,049	27,699	3,931	3,419	35,049
	0.31%	**1.51%**	**13.74%**	**0.11%**	**33.99%**	**0.33%**	**5.84%**	**55.83%**	**44.12%**	**6.26%**	**5.45%**	**55.83%**
	0.56%	*2.70%*	*24.60%*	*0.19%*	*60.88%*	*0.60%*	10.47%	*100.00%*	*79.03%*	*11.22%*	*9.75%*	*100.00%*
	67.71%	52.96%	49.81%	62.96%	59.23%	50.12%	53.66%	55.83%	59.00%	64.16%	35.22%	55.83%
Unknown	0	2	10	0	45	1	910	968	54	4	910	968
	0.00%	**0.00%**	**0.02%**	**0.00%**	**0.07%**	**0.00%**	*1.45%*	**1.54%**	**0.09%**	**0.01%**	**1.45%**	**1.54%**
	0.00%	*0.21%*	*1.03%*	0.00%	*4.63%*	*0.10%*	*94.01%*	*100.00%*	*5.58%*	*0.41%*	*94.01%*	*100.00%*
	0.00%	0.11%	0.06%	0.00%	0.12%	0.24%	13.31%	1.54%	0.12%	0.07%	9.37%	1.54%
Total	288	1,790	17,312	108	36,027	417	6,837	62,779	46,945	6,127	9,707	62,779
	0.46%	**2.85%**	**27.58%**	**0.17%**	**57.39%**	**0.66%**	**10.89%**	**100.00%**	**74.78%**	**9.76%**	**15.46%**	**100.00%**
	0.46%	*2.85%*	*27.58%*	*0.17%*	*57.39%*	*0.66%*	*10.89%*	*100.00%*	*74.78%*	*9.76%*	*15.46%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

TOTAL		TOTAL		TOTAL		OVERALL	
Females	118,082	Males	152,217	Unknown	1,991	Total	272,290
	43.37%		55.90%		0.73%		100%

Total Number of Protocols with Enrollment Data:	561

Table 14: Aggregate Enrollment Data for Extramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Reported in FY2003

Data Table Comments:

There were 831 protocols of which 189 were *female-only* protocols and 81 were *male-only* protocols.

Excluding sex-specific studies, the number of females (118,082 or 43.4%) to males (152,217 or 55.9%) enrolled in extramural research protocols are closely representative of the general population.

Largest identified racial group is Whites at 70% following the 1977 OMB standards and 57.4% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 14.7% following the 1977 OMB standards and 27.6% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives (0.5%).

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

9.7% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 10.2% of participants identified as Hispanic according to the 1977 OMB standards.

Table 15. Aggregate Enrollment Data for Extramural Phase III Research Protocols Reported in FY 2004: Percent Analysis

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

Number of Protocols with Enrollment Data:	273

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	860	4,286	25,434	13,345	158,846	3,231	206,002
	0.26%	**1.28%**	**7.61%**	**3.99%**	**47.50%**	**0.97%**	**61.60%**
	0.42%	*2.08%*	*12.35%*	*6.48%*	*77.11%*	*1.57%*	*100.00%*
	60.78%	67.90%	58.83%	57.14%	62.52%	53.48%	61.60%
Male	554	2,026	17,800	9,928	95,224	2,729	128,261
	0.17%	**0.61%**	**5.32%**	**2.97%**	**28.47%**	**0.82%**	**38.35%**
	0.43%	*1.58%*	*13.88%*	*7.74%*	*74.24%*	*2.13%*	*100.00%*
	39.15%	32.10%	41.17%	42.51%	37.48%	45.17%	38.35%
Unknown	1	0	1	83	5	82	172
	0.000%	**0.00%**	**0.00%**	**0.02%**	**0.00%**	**0.02%**	**0.05%**
	0.58%	*0.00%*	*0.58%*	*48.26%*	*2.91%*	*47.67%*	*100.00%*
	0.07%	0.00%	0.00%	0.36%	0.00%	1.36%	0.05%
Total	1,415	6,312	43,235	23,356	254,075	6,042	334,435
	0.42%	**1.89%**	**12.93%**	**6.98%**	**75.97%**	**1.81%**	**100.00%**
	0.42%	*1.89%*	*12.93%*	*6.98%*	*75.97%*	*1.81%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	266

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	802	1,657	18,865	114	38,304	2,078	1,893	63,713	55,738	5,051	2,924	63,713
	0.54%	**1.12%**	**12.76%**	**0.08%**	**25.90%**	**1.41%**	**1.28%**	**43.08%**	**37.69%**	**3.42%**	**1.98%**	**43.08%**
	1.26%	*2.60%*	*29.61%*	*0.18%*	*60.12%*	*3.26%*	*2.97%*	*100.00%*	*87.48%*	*7.93%*	*4.59%*	*100.00%*
	65.95%	45.61%	52.50%	25.85%	38.96%	54.16%	41.83%	43.08%	43.63%	40.02%	38.89%	43.08%
Male	414	1,976	17,063	327	59,967	1,759	1,745	83,271	72,006	7,569	3,696	83,271
	0.28%	**1.34%**	**11.54%**	**0.22%**	**40.56%**	**1.19%**	**1.18%**	**56.31%**	**48.69%**	**5.12%**	**2.50%**	**56.31%**
	0.50%	*2.37%*	*20.49%*	*0.39%*	*72.04%*	*2.11%*	2.10%	*100.00%*	*86.47%*	*9.09%*	*4.44%*	*100.00%*
	34.05%	54.39%	47.49%	74.15%	61.02%	45.84%	38.56%	56.31%	56.36%	59.97%	49.16%	56.31%
Unknown	0	0	2	0	16	0	888	906	7	1	898	906
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	***0.60%***	**0.61%**	**0.00%**	**0.00%**	**0.61%**	**0.61%**
	0.00%	*0.00%*	0.22%	*0.00%*	*1.77%*	*0.00%*	*98.01%*	*100.00%*	*0.77%*	*0.11%*	*99.12%*	*100.00%*
	0.00%	0.00%	0.01%	0.00%	0.02%	0.00%	19.62%	0.61%	0.01%	0.01%	11.94%	0.61%
Total	1,216	3,633	35,930	441	98,307	3,837	4,526	147,890	127,751	12,621	7,518	147,890
	0.82%	**2.46%**	**24.30%**	**0.30%**	**66.47%**	**2.59%**	**3.06%**	**100.00%**	**86.38%**	**8.53%**	**5.08%**	**100.00%**
	0.82%	*2.46%*	*24.30%*	*0.30%*	*66.47%*	*2.59%*	*3.06%*	*100.00%*	*86.38%*	*8.53%*	*5.08%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	269,715	Males	211,532	Unknown	1,078	Total	482,325
	55.92%		43.86%		0.22%		100%

Total Number of Protocols with Enrollment Data:	539

Table 15: Aggregate Enrollment Data for Extramural Phase III Research Protocols Reported in FY2004

Data Table Comments:

Substantial numbers of women and minorities are enrolled in Phase III research protocols reported in FY2004.

More females (269,715 or 55.9%) than males (211,532 or 43.8%) are enrolled in aggregate extramural research protocols.

Largest identified racial group is Whites at 77.9% following the 1977 OMB standards and 66.5% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 12.9% following the 1977 OMB standards and 24.3% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.4%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.30%).

8.5% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 7% of participants identified as Hispanic according to the 1977 OMB standards.

Table 16: Aggregate Enrollment Data for Extramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Reported in FY2004: Percent Analysis

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

Number of Protocols with Enrollment Data: 186

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/Other	Total
Female	330	1,359	13,121	8,366	42,839	1,492	67,507
	0.23%	**0.97%**	**9.34%**	**5.95%**	**30.48%**	**1.06%**	**48.04%**
	0.49%	*2.01%*	*19.44%*	*12.39%*	*63.46%*	*2.21%*	*100.00%*
	48.53%	49.71%	53.68%	53.60%	45.83%	41.57%	48.04%
Male	349	1,375	11,321	7,160	50,629	2,015	72,849
	0.25%	**0.98%**	**8.06%**	**5.10%**	**36.03%**	**1.43%**	**51.84%**
	0.48%	*1.89%*	*15.54%*	*9.83%*	*69.50%*	*2.77%*	*100.00%*
	51.32%	50.29%	46.32%	45.87%	54.16%	56.14%	51.84%
Unknown	1	0	1	83	5	82	172
	0.001%	**0.00%**	**0.00%**	**0.06%**	**0.00%**	**0.06%**	**0.12%**
	0.58%	*0.00%*	*0.58%*	*48.26%*	*2.91%*	*47.67%*	*100.00%*
	0.15%	0.00%	0.00%	0.53%	0.01%	2.28%	0.12%
Total	680	2,734	24,443	15,609	93,473	3,589	140,528
	0.48%	**1.96%**	**17.39%**	**11.11%**	**66.52%**	**2.55%**	**100.00%**
	0.48%	*1.95%*	*17.39%*	*11.11%*	*66.52%*	*2.55%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 175

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	466	814	14,948	86	23,295	1,485	966	42,060	36,540	2,799	2,721	42,060
	0.43%	**0.75%**	**13.72%**	**0.08%**	**21.39%**	**1.36%**	**0.89%**	**38.61%**	**33.55%**	**2.57%**	**2.50%**	**38.61%**
	1.11%	*1.94%*	*35.54%*	*0.20%*	*55.39%*	*3.53%*	*2.30%*	*100.00%*	*86.88%*	*6.65%*	*6.47%*	*100.00%*
	53.94%	40.32%	48.73%	20.92%	33.75%	48.51%	33.64%	38.61%	39.64%	28.36%	39.53%	38.61%
Male	398	1,205	15,729	323	45,713	1,576	1,018	65,962	55,630	7,068	3,264	65,962
	0.37%	**1.11%**	**14.44%**	**0.30%**	**41.97%**	**1.45%**	**0.93%**	**60.56%**	**51.07%**	**6.49%**	**3.00%**	**60.56%**
	0.60%	*1.83%*	*23.85%*	*0.49%*	*69.30%*	*2.39%*	1.54%	*100.00%*	*84.34%*	*10.72%*	*4.95%*	*100.00%*
	46.06%	59.68%	51.27%	78.59%	66.23%	51.49%	35.45%	60.56%	60.35%	71.63%	47.42%	60.56%
Unknown	0	0	0	2	16	0	888	906	7	1	898	906
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.01%**	**0.00%**	*0.82%*	**0.83%**	**0.01%**	**0.00%**	**0.82%**	**0.83%**
	0.00%	*0.00%*	0.00%	*0.22%*	*1.77%*	*0.00%*	*98.01%*	*100.00%*	*0.77%*	*0.11%*	*99.12%*	*100.00%*
	0.00%	0.00%	0.00%	0.49%	0.02%	0.00%	30.92%	0.83%	0.01%	0.01%	13.05%	0.83%
Total	864	2,019	30,677	411	69,024	3,061	2,872	108,928	92,177	9,868	6,883	108,928
	0.79%	**1.85%**	**28.16%**	**0.38%**	**63.37%**	**2.81%**	**2.64%**	**100.00%**	**84.62%**	**9.06%**	**6.32%**	**100.00%**
	0.79%	*1.85%*	*28.16%*	*0.38%*	*63.37%*	*2.81%*	2.64%	100.00%	*84.62%*	*9.06%*	*6.32%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		**TOTAL**		**TOTAL**		**OVERALL**	
Females	**109,567**	**Males**	**138,811**	**Unknown**	**1,078**	**Total**	**249,456**
	43.92%		**55.65%**		**0.43%**		**100%**

Total Number of Protocols with Enrollment Data: 361

Table 16: Aggregate Enrollment Data for Extramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Funded in FY2003 and Reported in FY2004

There were 831 protocols of which 147 were *female-only* protocols and 31 were *male-only* protocols.

Excluding sex-specific studies, the number of females (109,567 or 44%) to males (138,811 or 56%) enrolled in extramural research protocols are closely representative of the general population.

Largest identified racial group is Whites at 66.5% following the 1977 OMB standards and 63.4% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 17.4% following the 1977 OMB standards and 28.1% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives (0.5%).

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

9% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 11% of participants identified as Hispanic according to the 1977 OMB standards.

Table 17. Aggregate Enrollment Data for Intramural Research Protocols Reported in FY 2003: Percent Analysis

Number of Protocols with Enrollment Data: 1,199

Legend

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

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

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

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	9,511	128,639	52,418	35,421	585,064	57,453	868,506
	0.52%	**7.03%**	**2.86%**	**1.93%**	**31.96%**	**3.14%**	**47.43%**
	1.10%	*14.81%*	*6.04%*	*4.08%*	*67.36%*	*6.62%*	*100.00%*
	51.67%	66.93%	50.71%	60.71%	43.99%	44.65%	47.43%
Male	8,896	63,520	50,943	22,725	744,033	57,058	947,175
	0.49%	**3.47%**	**2.78%**	**1.24%**	**40.64%**	**3.12%**	**51.73%**
	0.94%	*6.71%*	*5.38%*	*2.40%*	*78.55%*	*6.02%*	*100.00%*
	48.33%	33.05%	49.28%	38.95%	55.94%	44.34%	51.73%
Unknown	0	41	10	200	870	14,165	15,286
	0.000%	**0.00%**	**0.00%**	**0.01%**	**0.05%**	**0.77%**	**0.83%**
	0.00%	*0.27%*	*0.07%*	*1.31%*	*5.69%*	*92.67%*	*100.00%*
	0.00%	0.02%	0.01%	0.34%	0.07%	11.01%	0.83%
Total	18,407	192,200	103,371	58,346	1,329,967	128,676	1,830,967
	1.01%	**10.50%**	**5.65%**	**3.19%**	**72.64%**	**7.03%**	**100.00%**
	1.01%	*10.50%*	*5.65%*	*3.19%*	*72.64%*	*7.03%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 156

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	2	75	312	1	1,024	3	107	1,524	1,388	99	37	1,524
	0.06%	**2.42%**	**10.07%**	**0.03%**	**33.06%**	**0.10%**	**3.45%**	**49.21%**	**44.82%**	**3.20%**	**1.19%**	**49.21%**
	0.13%	*4.92%*	*20.47%*	*0.07%*	*67.19%*	*0.20%*	*7.02%*	*100.00%*	*91.08%*	*6.50%*	*2.43%*	*100.00%*
	16.67%	41.67%	58.10%	100.00%	46.86%	50.00%	60.80%	49.21%	48.28%	60.74%	62.71%	49.21%
Male	10	105	225	0	1,161	3	69	1,573	1,487	64	22	1,573
	0.32%	**3.39%**	**7.27%**	**0.00%**	**37.49%**	**0.10%**	**2.23%**	**50.79%**	**48.01%**	**2.07%**	**0.71%**	**50.79%**
	0.64%	*6.68%*	*14.30%*	*0.00%*	*73.81%*	*0.19%*	4.39%	*100.00%*	*94.53%*	*4.07%*	*1.40%*	*100.00%*
	83.33%	58.33%	41.90%	0.00%	53.14%	50.00%	39.20%	50.79%	51.72%	39.26%	37.29%	50.79%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	***0.00%***	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	12	180	537	1	2,185	6	176	3,097	2,875	163	59	3,097
	0.39%	**5.81%**	**17.34%**	**0.03%**	**70.55%**	**0.19%**	**5.68%**	**100.00%**	**92.83%**	**5.26%**	**1.91%**	**100.00%**
	0.39%	*5.81%*	*17.34%*	*0.03%*	*70.55%*	*0.19%*	*5.68%*	*100.00%*	*92.83%*	*5.26%*	*1.91%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	870,030	Males	948,748	Unknown	15,286	Total	1,834,064
	47.44%		51.73%		0.83%		100%

Total Number of Protocols with Enrollment Data: 1,355

Table 17: Aggregate Enrollment Data for Intramural Research Protocols Reported in FY2003: Percent Analysis

Data Table Comments:

There were more males (947,748 or 51.7%) than females (870,030 or 47.5%) enrolled in aggregate intramural research protocols.

Differences in the enrollment of males and females is attributed primarily to improvements in reporting procedures (e.g. ensuring sex/gender declaration and recording at enrollment.

According to the 1977 OMB standards, the largest identified racial minority group is Asian/Pacific Islanders at (10.5%).

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives (1.01%).

According to the 1997 OMB standards, the largest identified racial minority group is Blacks at (17.3%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.03%).

5.3% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 3.2% of participants identified as Hispanics according to the 1977 OMB standards.

Table 18: Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2003

Number of Protocols with Enrollment Data: 1,021

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

	American Indian/ Alaska Native	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic**	**White**	**Unknown/ Other**	**Total**
Female	5	5910	222	118	2730	3439	12,424
	0.02%	**22.94%**	**0.86%**	**0.46%**	**10.60%**	**13.35%**	**48.22%**
	0.04%	*47.57%*	*1.79%*	*0.95%*	*21.97%*	*27.68%*	*100.00%*
	38.46%	48.63%	48.79%	47.39%	44.99%	50.39%	48.22%
Male	8	6244	233	131	3338	3386	13,340
	0.03%	**24.24%**	**0.90%**	**0.51%**	**12.96%**	**13.14%**	**51.78%**
	0.06%	*46.81%*	*1.75%*	*0.98%*	*25.02%*	*25.38%*	*100.00%*
	61.54%	51.37%	51.21%	52.61%	55.01%	49.61%	51.78%
Unknown	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	13	12,154	455	249	6,068	6,825	25,764
	0.05%	**47.17%**	**1.77%**	**0.97%**	**23.55%**	**26.49%**	**100.00%**
	0.05%	*47.17%*	*1.77%*	*0.97%*	*23.55%*	*26.49%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 115

	Total of All Subjects by Race								**Total of All Subjects by Ethnicities**			
	American Indian/ Alaska Native	**Asian**	**Black or African American**	**Hawaiian /Pacific Islander**	**White**	**More Than One Race**	**Unknown/Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown /Not Reported**	**Total**
Female	2	72	301	1	921	3	99	1,399	1,275	88	36	1,399
	0.07%	**2.55%**	**10.65%**	**0.04%**	**32.58%**	**0.11%**	**3.50%**	**49.49%**	**45.10%**	**3.11%**	**1.27%**	**49.49%**
	0.14%	*5.15%*	*21.52%*	*0.07%*	*65.83%*	*0.21%*	*7.08%*	*100.00%*	*91.14%*	*6.29%*	*2.57%*	*100.00%*
	22.22%	42.86%	58.90%	100.00%	46.70%	50.00%	61.88%	49.49%	48.55%	60.69%	64.29%	49.49%
Male	7	96	210	0	1,051	3	61	1,428	1,351	57	20	1,428
	0.25%	**3.40%**	**7.43%**	**0.00%**	**37.18%**	**0.11%**	**2.16%**	**50.51%**	**47.79%**	**2.02%**	**0.71%**	**50.51%**
	0.49%	*6.72%*	*14.71%*	*0.00%*	*73.60%*	*0.21%*	4.27%	*100.00%*	*94.61%*	*3.99%*	*1.40%*	*100.00%*
	77.78%	57.14%	41.10%	0.00%	53.30%	50.00%	38.13%	50.51%	51.45%	39.31%	35.71%	50.51%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	*0.00%*	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	9	169	511	1	1,972	6	160	2,827	2,626	145	56	2,827
	0.32%	**5.94%**	**18.08%**	**0.04%**	**69.76%**	**0.21%**	**5.66%**	**100.00%**	**92.89%**	**5.13%**	**1.98%**	**100.00%**
	0.32%	*5.94%*	18.08%	*0.04%*	69.76%	0.21%	5.66%	100.00%	92.89%	*5.13%*	1.98%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

TOTAL		**TOTAL**		**TOTAL**		**OVERALL**	
Females	**13,823**	**Males**	**14,768**	**Unknown**	**0**	**Total**	**28,591**
	48.35%		**51.65%**		**0.00%**		**100%**

Total Number of Protocols with Enrollment Data:	**1,136**

Table 18: Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2003

Data Table Comments:

There were 1,355 protocols of which 124 were *female-only* protocols and 95 were *male-only* protocols.

Excluding sex-specific studies, the number of females (13,823 or 48.4%) to males (14,768 or 51.6%) enrolled in intramural research protocols are closely representative of the general population.

Largest identified racial group is White at 23.5% following the 1977 OMB standards and 69.7% following the 1997 OMB standards.

Largest identified racial minority group is Asian/Pacific Islanders at 47.2% following the 1977 OMB standards.

Largest identified racial minority group is Blacks at 18.1% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.05%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.04%).

5.2% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards, whereas 0.97% of participants identified as Hispanic according to 1977 OMB standards.

Table 19. Aggregate Enrollment Data for Intramural Research Protocols Reported in FY 2004: Percent Analysis

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

Number of Protocols with Enrollment Data:	951

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	**9,537**	**131,618**	**54,306**	**50,267**	**599,553**	**53,061**	**898,342**
	0.51%	**6.99%**	**2.88%**	**2.67%**	**31.84%**	**2.82%**	**47.71%**
	1.06%	*14.65%*	*6.05%*	*5.60%*	*66.74%*	*5.91%*	*100.00%*
	51.40%	66.78%	51.42%	66.88%	44.20%	40.82%	47.71%
Male	**8,994**	**65,419**	**51,286**	**24,583**	**754,327**	**66,892**	**971,501**
	0.48%	**3.47%**	**2.72%**	**1.31%**	**40.06%**	**3.55%**	**51.59%**
	0.93%	*6.73%*	*5.28%*	*2.53%*	*77.65%*	*6.89%*	*100.00%*
	48.47%	33.19%	48.56%	32.71%	55.60%	51.46%	51.59%
Unknown	**23**	**41**	**16**	**308**	**2,724**	**10,036**	**13,148**
	0.001%	**0.00%**	**0.00%**	**0.02%**	**0.14%**	**0.53%**	**0.70%**
	0.17%	*0.31%*	*0.12%*	*2.34%*	*20.72%*	*76.33%*	*100.00%*
	0.12%	0.02%	0.02%	0.41%	0.20%	7.72%	0.70%
Total	18,554	197,078	105,608	75,158	1,356,604	129,989	1,882,991
	0.99%	**10.47%**	**5.61%**	**3.99%**	**72.05%**	**6.90%**	**100.00%**
	0.99%	*10.47%*	*5.61%*	*3.99%*	*72.05%*	*6.90%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	440

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	**546**	**1,173**	**3,130**	**2**	**38,286**	**8**	**1,630**	**44,774**	**43,487**	**1,156**	**131**	**44,774**
	0.85%	**1.83%**	**4.88%**	**0.00%**	**59.63%**	**0.01%**	**2.54%**	**69.74%**	**67.74%**	**1.80%**	**0.20%**	**69.74%**
	1.22%	*2.62%*	*6.99%*	*0.00%*	*85.51%*	*0.02%*	*3.64%*	*100.00%*	*97.13%*	*2.58%*	*0.29%*	*100.00%*
	76.33%	43.97%	53.35%	50.00%	75.79%	6.15%	37.90%	69.74%	70.78%	63.73%	13.83%	69.74%
Male	**169**	**1,012**	**2,456**	**2**	**11,074**	**12**	**738**	**15,463**	**14,919**	**454**	**90**	**15,463**
	0.26%	**1.58%**	**3.83%**	**0.00%**	**17.25%**	**0.02%**	**1.15%**	**24.09%**	**23.24%**	**0.71%**	**0.14%**	**24.09%**
	1.09%	*6.54%*	*15.88%*	*0.01%*	*71.62%*	*0.08%*	**4.77%**	*100.00%*	*96.48%*	*2.94%*	*0.58%*	*100.00%*
	23.67%	37.93%	41.86%	50.00%	21.92%	9.23%	17.16%	24.09%	24.28%	25.03%	9.50%	24.09%
Unknown	**0**	**483**	**281**	**0**	**1,157**	**110**	**1,933**	**3,964**	**3,034**	**204**	**726**	**3,964**
	0.00%	**0.75%**	**0.44%**	**0.00%**	**1.80%**	**0.17%**	*3.01%*	**6.17%**	**4.73%**	**0.32%**	**1.13%**	**6.17%**
	0.00%	*12.18%*	*7.09%*	**0.00%**	*29.19%*	*2.77%*	*48.76%*	*100.00%*	*76.54%*	*5.15%*	*18.31%*	*100.00%*
	0.00%	18.10%	4.79%	0.00%	2.29%	84.62%	44.94%	6.17%	4.94%	11.25%	76.66%	6.17%
Total	714	2,668	5,867	4	50,517	130	4,301	64,201	61,440	1,814	947	64,201
	1.11%	**4.16%**	**9.14%**	**0.01%**	**78.69%**	**0.20%**	**6.70%**	**100.00%**	**95.70%**	**2.83%**	**1.48%**	**100.00%**
	1.11%	*4.16%*	*9.14%*	*0.01%*	*78.69%*	*0.20%*	*6.70%*	*100.00%*	*95.70%*	*2.83%*	*1.48%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	943,116	Males	986,964	Unknown	28,611	Total	1,947,192
	48.43%		50.69%		1.47%		100%

Total Number of Protocols with Enrollment Data:	1,391

Table 19: Aggregate Enrollment Data for Intramural Research Protocols Reported in FY2004

Data Table Comments:

There were more males (986,964 or 50.7%) than females (943,116 or 48.4%) enrolled in aggregate intramural research protocols.

Differences in the enrollment of males and females is attributed primarily to improvements in reporting procedures (e.g. ensuring sex/gender declaration and recording at enrollment.

According to the 1977 OMB standards, the largest identified racial minority group is Asian Pacific Islanders at (10.47%).

According to the 1997 OMB standards, the largest identified racial minority group is Blacks at (9.14%).

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.1%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.01%).

2.8% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 4% of participants identified as Hispanic according to the 1977 OMB standards.

Table 20: Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2004

Number of Protocols with Enrollment Data: 823

Legend

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

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

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

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	9,259	53,482	45,637	18,354	496,634	45,115	668,481
	0.58%	**3.34%**	**2.85%**	**1.15%**	**30.98%**	**2.81%**	**41.70%**
	1.39%	*8.00%*	*6.83%*	*2.75%*	*74.29%*	*6.75%*	*100.00%*
	50.68%	45.01%	47.55%	42.46%	40.48%	45.29%	41.70%
Male	8,989	65,290	50,322	24,566	727,639	44,455	921,261
	0.56%	**4.07%**	**3.14%**	**1.53%**	**45.40%**	**2.77%**	**57.47%**
	0.98%	*7.09%*	*5.46%*	*2.67%*	*78.98%*	*4.83%*	*100.00%*
	49.20%	54.95%	52.43%	56.83%	59.30%	44.63%	57.47%
Unknown	23	41	16	308	2,724	10,036	13,148
	0.001%	**0.00%**	**0.00%**	**0.02%**	**0.17%**	**0.63%**	**0.82%**
	0.17%	*0.31%*	*0.12%*	*2.34%*	*20.72%*	*76.33%*	*100.00%*
	0.13%	0.03%	0.02%	0.71%	0.22%	10.08%	0.82%
Total	18,271	118,813	95,975	43,228	1,226,997	99,606	1,602,890
	1.14%	**7.41%**	**5.99%**	**2.70%**	**76.55%**	**6.21%**	**100.00%**
	1.14%	*7.41%*	*5.99%*	*2.70%*	*76.55%*	*6.21%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data: 349

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	375	898	2,693	2	10,824	8	526	15,326	14,831	370	125	15,326
	1.11%	**2.65%**	**7.94%**	**0.01%**	**31.92%**	**0.02%**	**1.55%**	**45.19%**	**43.73%**	**1.09%**	**0.37%**	**45.19%**
	2.45%	*5.86%*	*17.57%*	*0.01%*	*70.63%*	*0.05%*	*3.43%*	*100.00%*	*96.77%*	*2.41%*	*0.82%*	*100.00%*
	68.93%	37.70%	50.21%	66.67%	48.10%	6.15%	17.63%	45.19%	46.33%	38.38%	13.37%	45.19%
Male	169	1,001	2,390	1	10,524	12	525	14,622	14,148	390	84	14,622
	0.50%	**2.95%**	**7.05%**	**0.00%**	**31.03%**	**0.04%**	**1.55%**	**43.12%**	**41.72%**	**1.15%**	**0.25%**	**43.12%**
	1.16%	*6.85%*	*16.35%*	*0.01%*	*71.97%*	*0.08%*	3.59%	*100.00%*	*96.76%*	*2.67%*	*0.57%*	*100.00%*
	31.07%	42.02%	44.56%	33.33%	46.76%	9.23%	17.59%	43.12%	44.19%	40.46%	8.98%	43.12%
Unknown	0	483	281	0	1,157	110	1,933	3,964	3,034	204	726	3,964
	0.00%	**1.42%**	**0.83%**	**0.00%**	**3.41%**	**0.32%**	*5.70%*	**11.69%**	**8.95%**	**0.60%**	**2.14%**	**11.69%**
	0.00%	*12.18%*	*7.09%*	0.00%	*29.19%*	*2.77%*	*48.76%*	*100.00%*	*76.54%*	*5.15%*	*18.31%*	*100.00%*
	0.00%	20.28%	5.24%	0.00%	5.14%	84.62%	64.78%	11.69%	9.48%	21.16%	77.65%	11.69%
Total	544	2,382	5,364	3	22,505	130	2,984	33,912	32,013	964	935	33,912
	1.60%	**7.02%**	**15.82%**	**0.01%**	**66.36%**	**0.38%**	**8.80%**	**100.00%**	**94.40%**	**2.84%**	**2.76%**	**100.00%**
	1.60%	7.02%	15.82%	0.01%	66.36%	0.38%	8.80%	100.00%	94.40%	2.84%	2.76%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

TOTAL		**TOTAL**		**TOTAL**		**OVERALL**	
Females	**683,807**	**Males**	**935,883**	**Unknown**	**17,112**	**Total**	**1,636,802**
	41.78%		**57.18%**		**1.05%**		**100%**

Total Number of Protocols with Enrollment Data: **1,172**

Table 20: Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only and Female-Only Protocols Reported in FY2004

Data Table Comments:

There were 1,391 protocols of which 133 were *female-only* protocols and 86 were *male-only* protocols.

Excluding sex-specific studies, the number of females (683,807 or 41.8%) to males (935,883 or 57.2%) enrolled in intramural research protocols are closely representative of the general population.

Largest identified racial group is White at 76.5% following the 1977 OMB standards and 66.4% following the 1997 OMB standards.

Largest identified racial minority group is Asian/Pacific Islanders at 16% following the 1977 OMB standards.

Largest identified racial minority group is Blacks at 15.8% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (1.14%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.01%).

2.8% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards, whereas 2.7% of participants identified as Hispanic according to 1977 OMB standards.

Table 21. Aggregate Enrollment for Intramural Phase III Research Protocols Reported in FY 2003: Percent Analysis

Number of Protocols with Enrollment Data:	29

Legend

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

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

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

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	5	5910	222	118	2730	3439	12,424
	0.02%	**22.94%**	**0.86%**	**0.46%**	**10.60%**	**13.35%**	**48.22%**
	0.04%	*47.57%*	*1.79%*	*0.95%*	*21.97%*	*27.68%*	*100.00%*
	38.46%	48.63%	48.79%	47.39%	44.99%	50.39%	48.22%
Male	8	6244	233	131	3338	3386	13,340
	0.03%	**24.24%**	**0.90%**	**0.51%**	**12.96%**	**13.14%**	**51.78%**
	0.06%	*46.81%*	*1.75%*	*0.98%*	*25.02%*	*25.38%*	*100.00%*
	61.54%	51.37%	51.21%	52.61%	55.01%	49.61%	51.78%
Unknown	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	13	12,154	455	249	6,068	6,825	25,764
	0.05%	**47.17%**	**1.77%**	**0.97%**	**23.55%**	**26.49%**	**100.00%**
	0.05%	*47.17%*	*1.77%*	*0.97%*	*23.55%*	*26.49%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	4

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	0	2	70	1	80	1	11	165	153	8	4	165
	0.00%	**0.78%**	**27.45%**	**0.39%**	**31.37%**	**0.39%**	**4.31%**	**64.71%**	**60.00%**	**3.14%**	**1.57%**	**64.71%**
	0.00%	*1.21%*	*42.42%*	*0.61%*	*48.48%*	*0.61%*	*6.67%*	*100.00%*	*92.73%*	*4.85%*	*2.42%*	*100.00%*
	0.00%	28.57%	78.65%	100.00%	56.74%	100.00%	68.75%	64.71%	64.29%	66.67%	80.00%	64.71%
Male	0	5	19	0	61	0	5	90	85	4	1	90
	0.00%	**1.96%**	**7.45%**	**0.00%**	**23.92%**	**0.00%**	**1.96%**	**35.29%**	**33.33%**	**1.57%**	**0.39%**	**35.29%**
	0.00%	*5.56%*	*21.11%*	*0.00%*	*67.78%*	*0.00%*	5.56%	*100.00%*	*94.44%*	*4.44%*	*1.11%*	*100.00%*
	0.00%	71.43%	21.35%	0.00%	43.26%	0.00%	31.25%	35.29%	35.71%	33.33%	20.00%	35.29%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	7	89	1	141	1	16	255	238	12	5	255
	0.00%	**2.75%**	**34.90%**	**0.39%**	**55.29%**	**0.39%**	**6.27%**	**100.00%**	**93.33%**	**4.71%**	**1.96%**	**100.00%**
	0.00%	*2.75%*	*34.90%*	*0.39%*	*55.29%*	*0.39%*	*6.27%*	*100.00%*	*93.33%*	*4.71%*	*1.96%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	12,589	Males	13,430	Unknown	0	Total	26,019
	48.38%		51.62%		0.00%		100%

Total Number of Protocols with Enrollment Data:	33

Table 21: Aggregate Enrollment Data for Intramural Phase III Research Protocols Reported in FY2003

Data Table Comments:

There were more males (13,430 or 51.6%) than females (12,589 or 48.3%) enrolled in aggregate intramural research protocols.

Differences in the enrollment of males and females is attributed primarily to improvements in reporting procedures (e.g. ensuring sex/gender declaration and recording at enrollment.

According to the 1977 OMB standards, the largest identified racial minority group is Asian and Pacific Islanders at (47.17%).

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native (0.05%).

According to the 1997 OMB standards, the largest identified racial minority group is Blacks at (34.9%).

According to the 1997 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native (0%).

4.71% of participants identified their ethnicity as Hispanic or Latino, following the 1997 OMB standards wheras 0.97% of participants identified as Hispanic or Latino.

Table 22: Aggregate Enrollment Data for Intramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Reported in FY2003:

Number of Protocols with Enrollment Data: 28

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	5	5,910	222	118	2,730	3,439	12,424
	0.02%	**22.96%**	**0.86%**	**0.46%**	**10.61%**	**13.36%**	**48.26%**
	0.04%	*47.57%*	*1.79%*	*0.95%*	*21.97%*	*27.68%*	*100.00%*
	41.67%		49.22%	47.39%	45.10%	50.39%	48.26%
Male	7	6,242	229	131	3,322	3,386	13,317
	0.03%	**24.25%**	**0.89%**	**0.51%**	**12.90%**	**13.15%**	**51.73%**
	0.05%	*46.87%*	*1.72%*	*0.98%*	*24.95%*	*25.43%*	*100.00%*
	58.33%	51.37%	50.78%	52.61%	54.88%	49.61%	51.73%
Unknown	0	0	0	0	1	0	1
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*100.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	0.00%	0.00%	0.02%	0.00%	0.00%
Total	12	12,152	451	249	6,053	6,825	25,742
	0.05%	**47.21%**	**1.75%**	**0.97%**	**23.51%**	**26.51%**	**100.00%**
	0.05%	*47.21%*	*1.75%*	*0.97%*	*23.51%*	*26.51%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Number of Protocols with Enrollment Data: 2

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	0	2	70	1	80	1	11	165	153	8	4	165
	0.00%	**0.82%**	**28.69%**	**0.41%**	**32.79%**	**0.41%**	**4.51%**	**67.62%**	**62.70%**	**3.28%**	**1.64%**	**67.62%**
	0.00%	*1.21%*	*42.42%*	*0.61%*	*48.48%*	*0.61%*	*6.67%*	*100.00%*	*92.73%*	*4.85%*	*2.42%*	*100.00%*
	0.00%	28.57%	78.65%	100.00%	61.07%	100.00%	73.33%	67.62%	67.11%	72.73%	80.00%	67.62%
Male	0	5	19	0	51	0	4	79	75	3	1	79
	0.00%	**2.05%**	**7.79%**	**0.00%**	**20.90%**	**0.00%**	**1.64%**	**32.38%**	**30.74%**	**1.23%**	**0.41%**	**32.38%**
	0.00%	*6.33%*	*24.05%*	*0.00%*	*64.56%*	*0.00%*	5.06%	*100.00%*	*94.94%*	*3.80%*	*1.27%*	*100.00%*
	0.00%	71.43%	21.35%	0.00%	38.93%	0.00%	26.67%	32.38%	32.89%	27.27%	20.00%	32.38%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	*0.00%*	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	7	89	1	131	1	15	244	228	11	5	244
	0.00%	**2.87%**	**36.48%**	**0.41%**	**53.69%**	**0.41%**	**6.15%**	**100.00%**	**93.44%**	**4.51%**	**2.05%**	**100.00%**
	0.00%	2.87%	36.48%	0.41%	53.69%	0.41%	6.15%	100.00%	93.44%	4.51%	2.05%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form

TOTAL		TOTAL		TOTAL		OVERALL	
Females	12,589	Males	13,396	Unknown	1	Total	25,986
	48.45%		51.55%		0.00%		100%

Total Number of Protocols with Enrollment Data: 30

Table 22: Aggregate Enrollment Data for Intramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Reported in FY2003

Data Table Comments:

Excluding sex-specific studies, the number of females (12,589 or 48.4%) to males (13,396 or 51.5%) enrolled in intramural research protocols are closely representative of the general population.

Largest identified racial group is Whites at 23.5% following the 1977 OMB standards and 53.7% following the 1997 OMB standards.

Largest identified racial minority group is Asian/Pacific Islanders at 47.2% following the 1977 OMB standards.

Largest identified racial minority group is Black at 36.5% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives (0.05%) and 0% following the 1997 OMB standards.

4.51% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 0.97% of participants identified as Hispanic according to the 1977 OMB standards.

Table 23. Intramural Phase III Research Protocols Reported in FY 2004: Percent Analysis

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	9	5966	364	4948	1449	3919	16,655
	0.03%	**17.88%**	**1.09%**	**14.83%**	**4.34%**	**11.74%**	**49.90%**
	0.05%	*35.82%*	*2.19%*	*29.71%*	*8.70%*	*23.53%*	*100.00%*
	37.50%	48.65%	50.70%	56.68%	37.94%	50.10%	49.90%
Male	15	6296	354	3781	2370	3903	16,719
	0.04%	**18.86%**	**1.06%**	**11.33%**	**7.10%**	**11.69%**	**50.10%**
	0.09%	*37.66%*	*2.12%*	*22.61%*	*14.18%*	*23.34%*	*100.00%*
	62.50%	51.35%	49.30%	43.32%	62.06%	49.90%	50.10%
Unknown	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	24	12,262	718	8,729	3,819	7,822	33,374
	0.07%	**36.74%**	**2.15%**	**26.16%**	**11.44%**	**23.44%**	**100.00%**
	0.07%	*36.74%*	*2.15%*	*26.16%*	*11.44%*	*23.44%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data: 25

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 12

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	2	4	162	1	233	1	28	431	401	21	9	431
	0.30%	**0.61%**	**24.51%**	**0.15%**	**35.25%**	**0.15%**	**4.24%**	**65.20%**	**60.67%**	**3.18%**	**1.36%**	**65.20%**
	0.46%	*0.93%*	*37.59%*	*0.23%*	*54.06%*	*0.23%*	*6.50%*	*100.00%*	*93.04%*	*4.87%*	*2.09%*	*100.00%*
	66.67%	28.57%	78.64%	100.00%	58.84%	50.00%	71.79%	65.20%	64.78%	72.41%	69.23%	65.20%
Male	1	10	44	0	163	1	11	230	218	8	4	230
	0.15%	**1.51%**	**6.66%**	**0.00%**	**24.66%**	**0.15%**	**1.66%**	**34.80%**	**32.98%**	**1.21%**	**0.61%**	**34.80%**
	0.43%	*4.35%*	*19.13%*	*0.00%*	*70.87%*	*0.43%*	4.78%	*100.00%*	*94.78%*	*3.48%*	*1.74%*	*100.00%*
	33.33%	71.43%	21.36%	0.00%	41.16%	50.00%	28.21%	34.80%	35.22%	27.59%	30.77%	34.80%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	***0.00%***	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	3	14	206	1	396	2	39	661	619	29	13	661
	0.45%	**2.12%**	**31.16%**	**0.15%**	**59.91%**	**0.30%**	**5.90%**	**100.00%**	**93.65%**	**4.39%**	**1.97%**	**100.00%**
	0.45%	*2.12%*	*31.16%*	*0.15%*	*59.91%*	*0.30%*	5.90%	100.00%	93.65%	4.39%	1.97%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	17,086	Males	16,949	Unknown	0	Total	34,035
	50.20%		49.80%		0.00%		100%

Total Number of Protocols with Enrollment Data: 37

Table 23: Aggregate Enrollment Data for Intramural Phase III Research Protocols Reported in FY2004

Data Table Comments:

There were more females (17,086 or 50.2%) than males (16,949 or 49.8%) enrolled in aggregate intramural research protocols.

Differences in the enrollment of males and females is attributed primarily to improvements in reporting procedures (e.g. ensuring sex/gender declaration and recording at enrollment.

According to the 1977 OMB standards, the largest identified racial minority group is Asian Pacific Islander at (36.74%).

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native (0.07%).

According to the 1997 OMB standards, the largest identified racial minority group is Blacks at (31.2%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.15%).

4.4% of participants identified their ethnicity as Hispanic or Latino. Whereas 26% of participants identified as Hispanic according to the 1977 OMB standards.

Table 24: Aggregate Enrollment Data for Intramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Reported in FY2004:

Number of Protocols with Enrollment Data: 24

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	9	5,966	364	4,948	1,449	3,919	16,655
	0.03%	**17.89%**	**1.09%**	**14.84%**	**4.34%**	**11.75%**	**49.94%**
	0.05%	*35.82%*	*2.19%*	*29.71%*	*8.70%*	*23.53%*	*100.00%*
	39.13%	48.66%	50.98%	56.69%	38.11%	50.10%	49.94%
Male	14	6,294	350	3,780	2,353	3,903	16,694
	0.04%	**18.87%**	**1.05%**	**11.33%**	**7.06%**	**11.70%**	**50.06%**
	0.08%	*37.70%*	*2.10%*	*22.64%*	*14.09%*	*23.38%*	*100.00%*
	60.87%	51.34%	49.02%	43.31%	61.89%	49.90%	50.06%
Unknown	0	0	0	0	0	0	0
	0.000%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*100.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	23	12,260	714	8,728	3,802	7,822	33,349
	0.07%	**36.76%**	**2.14%**	**26.17%**	**11.40%**	**23.45%**	**100.00%**
	0.07%	*36.76%*	*2.14%*	*26.17%*	*11.40%*	*23.45%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Number of Protocols with Enrollment Data: 10

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	Not Hispanic	Hispanic or Latino	Unknown /Not Reported	Total
Female	2	4	162	1	233	1	28	431	401	21	9	431
	0.31%	**0.62%**	**25.12%**	**0.16%**	**36.12%**	**0.16%**	**4.34%**	**66.82%**	**62.17%**	**3.26%**	**1.40%**	**66.82%**
	0.46%	*0.93%*	*37.59%*	*0.23%*	*54.06%*	*0.23%*	*6.50%*	*100.00%*	*93.04%*	*4.87%*	*2.09%*	*100.00%*
	66.67%	28.57%	78.64%	100.00%	61.15%	50.00%	73.68%	66.82%	66.39%	75.00%	69.23%	66.82%
Male	1	10	44	0	148	1	10	214	203	7	4	214
	0.16%	**1.55%**	**6.82%**	**0.00%**	**22.95%**	**0.16%**	**1.55%**	**33.18%**	**31.47%**	**1.09%**	**0.62%**	**33.18%**
	0.47%	*4.67%*	*20.56%*	*0.00%*	*69.16%*	*0.47%*	4.67%	*100.00%*	*94.86%*	*3.27%*	*1.87%*	*100.00%*
	33.33%	71.43%	21.36%	0.00%	38.85%	50.00%	26.32%	33.18%	33.61%	25.00%	30.77%	33.18%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**	***0.00%***	**0.00%**	**0.00%**	**0.00%**	**0.00%**	**0.00%**
	0.00%	0.00%	0.00%	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*	*0.00%*
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	3	14	206	1	381	2	38	645	604	28	13	645
	0.47%	**2.17%**	**31.94%**	**0.16%**	**59.07%**	**0.31%**	**5.89%**	**100.00%**	**93.64%**	**4.34%**	**2.02%**	**100.00%**
	0.47%	2.17%	31.94%	*0.16%*	*59.07%*	0.31%	5.89%	*100.00%*	93.64%	4.34%	2.02%	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		**TOTAL**		**TOTAL**		**OVERALL**	
Females	**17,086**	**Males**	**16,908**	**Unknown**	**0**	**Total**	**33,994**
	50.26%		**49.74%**		**0.00%**		**100%**

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

Table 24: Aggregate Enrollment Data for Intramural Phase III Protocols, Excluding Male-Only and Female-Only Protocols Reported in FY2004

Data Table Comments:

Excluding sex-specific studies, the number of females (17,086 or 50.3%) to males (16,908 or 49.7%) enrolled in intramural research protocols are closely representative of the general population.

Largest identified racial minority group is Asian/Pacific Islanders at 36.8% following the 1977 OMB standards.

Largest identified racial minority group is Blacks at 31.9% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives (0.07%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.16%).

4.3% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 26.2% of participants identified as Hispanic according to the 1977 OMB standards.

Table C03. Examples of Single Sex Extramural Research Studies Reported in FY2003

	Extramural Studies		**Intramural Studies**	
	Phase III trials*	Other Clinical trials**	On-Site	Off-Site
Protocols reporting women only	189	1091	84	40
Protocols reporting men only	81	438	78	17
Protocols reporting both men and women	525	6057	904	190
Protocols reporting men, women, and unknown	33	378	5	28
Protocols reporting sex composition as unknown only	1	56	0	6
Protocols reporting men and unknown	0	2	0	1
Protocols reports women and unknown	2	8	0	2
Early Stage studies where enrollment data has not yet been submitted	113	3712	0	0
Totals	**944**	**11742**	**1071**	**284**

* According to the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Phase III clinical investigations usually involve several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments.

** Human subject studies that are not Phase III trials.

Table C04. Examples of Single Sex Extramural Research Studies Reported in FY2004

	Extramural Studies		Intramural Studies	
	Phase III trials*	Other Clinical trials**	On-Site	Off-Site
Protocols reporting women only	147	1189	93	40
Protocols reporting men only	31	395	71	15
Protocols reporting both men and women	337	6112	917	207
Protocols reporting men, women, and unknown	17	441	6	27
Protocols reporting sex composition as unknown only	2	54	0	12
Protocols reporting men and unknown	3	3	0	1
Protocols reports women and unknown	3	0	0	2
Early Stage studies where enrollment data has not yet been submitted	110	3951	221	105
Totals	**650**	**12145**	**1308**	**409**

* According to the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Phase III clinical investigations usually involve several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments.

** Human subject studies that are not Phase III trials.

Table 25. Domestic Enrollment: Aggregate Data, NIH Domestic Research Protocols Reported in FY 2003: Percent Analysis

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

	American Indian/ Alaska Native	Asian / Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	18,296	172,919	270,626	157,927	1,687,950	135,081	2,442,799
	0.42%	**3.95%**	**6.19%**	**3.61%**	**38.60%**	**3.09%**	**55.87%**
	0.75%	*7.08%*	*11.08%*	*6.47%*	*69.10%*	*5.53%*	*100.00%*
	50.49%	69.33%	59.44%	59.74%	54.44%	50.72%	55.87%
Male	15,883	69,421	182,183	105,197	1,404,982	108,906	1,886,572
	0.36%	**1.59%**	**4.17%**	**2.41%**	**32.13%**	**2.49%**	**43.15%**
	0.84%	*3.68%*	*9.66%*	*5.58%*	*74.47%*	*5.77%*	*100.00%*
	43.83%	27.83%	40.01%	39.80%	45.31%	40.89%	43.15%
Unknown	2,059	7,080	2,520	1,212	7,883	22,352	43,106
	0.047%	**0.16%**	**0.06%**	**0.03%**	**0.18%**	**0.51%**	**0.99%**
	4.78%	*16.42%*	*5.85%*	*2.81%*	*18.29%*	*51.85%*	*100.00%*
	5.68%	2.84%	0.55%	0.46%	0.25%	8.39%	0.99%
Total	36,238	249,420	455,329	264,336	3,100,815	266,339	4,372,477
	0.83%	**5.70%**	**10.41%**	**6.05%**	**70.92%**	**6.09%**	**100.00%**
	0.83%	*5.70%*	*10.41%*	*6.05%*	*70.92%*	*6.09%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:	4,478

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	5,100

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	41,963	167,849	563,265	11,234	3,371,751	52,717	740,826	4,949,605	3,883,020	373,409	693,176	4,949,605
	0.56%	**2.23%**	**7.47%**	**0.15%**	**44.72%**	**0.70%**	**9.83%**	**65.65%**	**51.51%**	**4.95%**	**9.19%**	**65.65%**
	0.85%	*3.39%*	*11.38%*	*0.23%*	*68.12%*	*1.07%*	*14.97%*	*100.00%*	*78.45%*	*7.54%*	*14.00%*	*100.00%*
	68.20%	56.89%	62.76%	48.70%	65.32%	56.00%	73.67%	65.65%	64.68%	62.03%	74.25%	65.65%
Male	18,189	125,500	328,467	10,563	1,775,363	40,973	207,869	2,506,924	2,104,749	226,412	175,763	2,506,924
	0.24%	**1.66%**	**4.36%**	**0.14%**	**23.55%**	**0.54%**	**2.76%**	**33.25%**	**27.92%**	**3.00%**	**2.33%**	**33.25%**
	0.73%	*5.01%*	*13.10%*	*0.42%*	*70.82%*	*1.63%*	8.29%	*100.00%*	*83.96%*	*9.03%*	*7.01%*	*100.00%*
	29.56%	42.53%	36.60%	45.79%	34.39%	43.52%	20.67%	33.25%	35.06%	37.61%	18.83%	33.25%
Unknown	1,374	1,712	5,786	1,271	14,851	448	56,909	82,351	15,557	2,197	64,597	82,351
	0.02%	**0.02%**	**0.08%**	**0.02%**	**0.20%**	**0.01%**	*0.75%*	**1.09%**	**0.21%**	**0.03%**	**0.86%**	**1.09%**
	1.67%	*2.08%*	7.03%	*1.54%*	*18.03%*	*0.54%*	*69.11%*	*100.00%*	*18.89%*	*2.67%*	*78.44%*	*100.00%*
	2.23%	0.58%	0.64%	5.51%	0.29%	0.48%	5.66%	1.09%	0.26%	0.36%	6.92%	1.09%
Total	61,526	295,061	897,518	23,068	5,161,965	94,138	1,005,604	7,538,880	6,003,326	602,018	933,536	7,538,880
	0.82%	**3.91%**	**11.91%**	**0.31%**	**68.47%**	**1.25%**	**13.34%**	**100.00%**	**79.63%**	**7.99%**	**12.38%**	**100.00%**
	0.82%	3.91%	11.91%	0.31%	68.47%	1.25%	13.34%	100.00%	79.63%	7.99%	12.38%	100.00%
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	7,392,404	Males	4,393,496	Unknown	125,457	Total	11,911,357
	62.06%		36.88%		1.05%		100%

Total Number of Protocols with Enrollment Data:	9,578

Table 25. Domestic Enrollment: Aggregate Data, NIH Domestic Research Protocols Reported in FY 2003: Percent Analysis

Data Table Comments:

More females (7,392,404 or 62.06%) than males (4,393,496 or 37%) are enrolled in aggregate extramural research protocols.

Largest identified racial group is Whites at 70.9% following the 1977 OMB standards and 68.47% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 10.4% following the 1977 OMB standards and 11.9% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.83%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.31%).

8% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Wwhereas, 6% of participants identified as Hispanic according to the 1977 standards.

Table 26. Domestic Enrollment: Aggregate Data for NIH Domestic Research Protocols Reported in FY 2004: Percent Analysis

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

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	15,665	146,862	193,556	119,460	1,188,556	68,175	1,732,274
	0.49%	**4.63%**	**6.10%**	**3.76%**	**37.45%**	**2.15%**	**54.59%**
	0.90%	*8.48%*	*11.17%*	*6.90%*	*68.61%*	*3.94%*	*100.00%*
	54.10%	74.68%	60.10%	61.34%	52.28%	43.30%	54.59%
Male	13,189	49,543	128,211	74,263	1,080,055	74,819	1,420,080
	0.42%	**1.56%**	**4.04%**	**2.34%**	**34.03%**	**2.36%**	**44.75%**
	0.93%	*3.49%*	*9.03%*	*5.23%*	*76.06%*	*5.27%*	*100.00%*
	45.55%	25.19%	39.81%	38.13%	47.50%	47.51%	44.75%
Unknown	99	242	311	1,039	5,008	14,470	21,169
	0.003%	**0.01%**	**0.01%**	**0.03%**	**0.16%**	**0.46%**	**0.67%**
	0.47%	*1.14%*	*1.47%*	*4.91%*	*23.66%*	*68.35%*	*100.00%*
	0.34%	0.12%	0.10%	0.53%	0.22%	9.19%	0.67%
Total	28,953	196,647	322,078	194,762	2,273,619	157,464	3,173,523
	0.91%	**6.20%**	**10.15%**	**6.14%**	**71.64%**	**4.96%**	**100.00%**
	0.91%	*6.20%*	*10.15%*	*6.14%*	*71.64%*	*4.96%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Number of Protocols with Enrollment Data:	2,702

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	7,058

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	66,494	274,214	783,839	22,590	4,927,033	96,490	978,365	7,149,025	5,569,115	454,514	1,125,396	7,149,025
	0.59%	**2.45%**	**7.01%**	**0.20%**	**44.05%**	**0.86%**	**8.75%**	**63.91%**	**49.79%**	**4.06%**	**10.06%**	**63.91%**
	0.93%	*3.84%*	*10.96%*	*0.32%*	*68.92%*	*1.35%*	*13.69%*	*100.00%*	*77.90%*	*6.36%*	*15.74%*	*100.00%*
	67.95%	56.52%	61.23%	52.60%	63.39%	56.04%	73.28%	63.91%	62.62%	63.08%	71.56%	63.91%
Male	29,796	198,607	480,461	18,087	2,695,954	74,117	282,663	3,779,685	3,148,534	259,926	371,225	3,779,685
	0.27%	**1.78%**	**4.30%**	**0.16%**	**24.10%**	**0.66%**	**2.53%**	**33.79%**	**28.15%**	**2.32%**	**3.32%**	**33.79%**
	0.79%	*5.25%*	*12.71%*	*0.48%*	*71.33%*	*1.96%*	7.48%	*100.00%*	*83.30%*	*6.88%*	*9.82%*	*100.00%*
	30.45%	40.94%	37.53%	42.12%	34.68%	43.04%	21.17%	33.79%	35.40%	36.07%	23.61%	33.79%
Unknown	1,564	12,316	15,829	2,268	149,940	1,578	74,065	257,580	175,509	6,111	75,940	257,580
	0.01%	**0.11%**	**0.14%**	**0.02%**	**1.34%**	**0.01%**	*0.66%*	**2.30%**	**1.57%**	**0.05%**	**0.68%**	**2.30%**
	0.61%	*4.78%*	*6.15%*	0.88%	*58.22%*	*0.61%*	*28.76%*	*100.00%*	*68.14%*	*2.37%*	*29.48%*	*100.00%*
	1.60%	2.54%	1.24%	5.28%	1.93%	0.92%	5.55%	2.30%	1.97%	0.85%	4.83%	2.30%
Total	97,854	485,137	1,280,129	42,945	7,772,927	172,185	1,335,093	11,186,270	8,893,158	720,551	1,572,561	11,186,270
	0.87%	**4.34%**	**11.44%**	**0.38%**	**69.49%**	**1.54%**	**11.94%**	**100.00%**	**79.50%**	**6.44%**	**14.06%**	**100.00%**
	0.87%	*4.34%*	*11.44%*	*0.38%*	*69.49%*	*1.54%*	*11.94%*	*100.00%*	*79.50%*	*6.44%*	*14.06%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form

TOTAL		TOTAL		TOTAL		OVERALL	
Females	8,881,299	Males	5,199,765	Unknown	278,729	Total	14,359,793
	61.85%		36.21%		1.94%		100%

Total Number of Protocols with Enrollment Data:	9,760

Table 26. Domestic Enrollment: Aggregate Data for NIH Domestic Research Protocols Reported in FY 2004: Percent Analysis

Data Table Comments:

More females (8,871,299 or 61.8%) than males (5,199,765 or 36.2%) are enrolled in aggregate extramural research protocols.

Largest identified racial group is Whites at 71.6% following the 1977 OMB standards and 69.5% following the 1997 OMB standards.

Largest identified racial minority group is Blacks at 10% following the 1977 OMB standards and 11.4% following the 1997 OMB standards.

According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Natives at (0.91%).

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islanders at (0.38%).

6.5% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas 6% of participants identified as Hispanic or Latino according to the 1977 OMB standards.

Table 27. Foreign Enrollment: Aggregate Data, NIH Foreign Research Protocols Reported in FY 2003: Percent Analysis

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

Number of Protocols with Enrollment Data:	425

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	179	243,429	12,189	19,503	56,793	4,064	336,157
	0.03%	**36.18%**	**1.81%**	**2.90%**	**8.44%**	**0.60%**	**49.97%**
	0.05%	*72.42%*	*3.63%*	*5.80%*	*16.89%*	*1.21%*	*100.00%*
	52.49%	50.60%	71.29%	80.63%	41.31%	32.35%	49.97%
Male	162	237,652	4,908	4,402	80,672	4,847	332,643
	0.02%	**35.32%**	**0.73%**	**0.65%**	**11.99%**	**0.72%**	**49.44%**
	0.05%	*71.44%*	*1.48%*	*1.32%*	*24.25%*	*1.46%*	*100.00%*
	47.51%	49.40%	28.71%	18.20%	58.68%	38.58%	49.44%
Unknown	0	41	0	282	4	3,651	3,978
	0.000%	**0.01%**	**0.00%**	**0.04%**	**0.00%**	**0.54%**	**0.59%**
	0.00%	*1.03%*	*0.00%*	*7.09%*	*0.10%*	*91.78%*	*100.00%*
	0.00%	0.01%	0.00%	1.17%	0.00%	29.06%	0.59%
Total	341	481,122	17,097	24,187	137,469	12,562	672,778
	0.05%	**71.51%**	**2.54%**	**3.60%**	**20.43%**	**1.87%**	**100.00%**
	0.05%	*71.51%*	*2.54%*	*3.60%*	*20.43%*	*1.87%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data:	213

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	959	601,409	39,428	4,924	132,517	2,973	3,710	785,920	770,380	5,199	10,341	785,920
	0.04%	**27.49%**	**1.80%**	**0.23%**	**6.06%**	**0.14%**	**0.17%**	**35.92%**	**35.21%**	**0.24%**	**0.47%**	**35.92%**
	0.12%	*76.52%*	*5.02%*	*0.63%*	*16.86%*	*0.38%*	*0.47%*	*100.00%*	*98.02%*	*0.66%*	*1.32%*	*100.00%*
	47.52%	32.63%	63.01%	33.96%	52.22%	55.84%	52.86%	35.92%	35.68%	54.03%	52.86%	35.92%
Male	1,050	1,241,532	21,101	5,075	121,145	2,351	3,103	1,395,357	1,383,710	4,420	7,227	1,395,357
	0.05%	**56.74%**	**0.96%**	**0.23%**	**5.54%**	**0.11%**	**0.14%**	**63.77%**	**63.24%**	**0.20%**	**0.33%**	**63.77%**
	0.08%	*88.98%*	*1.51%*	*0.36%*	*8.68%*	*0.17%*	0.22%	*100.00%*	*99.17%*	*0.32%*	*0.52%*	*100.00%*
	52.03%	67.37%	33.72%	35.00%	47.74%	44.16%	44.21%	63.77%	64.09%	45.93%	36.94%	63.77%
Unknown	9	0	2,043	4,502	83	0	205	6,842	4,843	4	1,995	6,842
	0.00%	**0.00%**	**0.09%**	**0.21%**	**0.00%**	**0.00%**	*0.01%*	**0.31%**	**0.22%**	**0.00%**	**0.09%**	**0.31%**
	0.13%	*0.00%*	29.86%	*65.80%*	*1.21%*	*0.00%*	*3.00%*	*100.00%*	*70.78%*	*0.06%*	*29.16%*	*100.00%*
	0.45%	0.00%	3.27%	31.05%	0.03%	0.00%	2.92%	0.31%	0.22%	0.04%	10.20%	0.31%
Total	2,018	1,842,941	62,572	14,501	253,745	5,324	7,018	2,188,119	2,158,933	9,623	19,563	2,188,119
	0.09%	**84.22%**	**2.86%**	**0.66%**	**11.60%**	**0.24%**	**0.32%**	**100.00%**	**98.67%**	**0.44%**	**0.89%**	**100.00%**
	0.09%	84.22%	2.86%	0.66%	*11.60%*	0.24%	0.32%	*100.00%*	98.67%	0.44%	0.89%	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	1,122,077	Males	1,728,000	Unknown	10,820	Total	2,860,897
	39.22%		60.40%		0.38%		100%

Total Number of Protocols with Enrollment Data:	638

Table 27. Foreign Enrollment: Aggregate Data, NIH Foreign Research Protocols Reported in FY 2003: Percent Analysis

Data Table Comments:

More males (1,728,000 or 60.4%) than females (1,122,077 or 39.2%) are enrolled in aggregate extramural research protocols.

Largest identified racial minority group is Asian Pacific Islanders at 71.5% following the 1977 OMB standards and 84.2% following the 1997 OMB standards.

The smallest identified racial minority group is American Indian/Alaskan Native at (0.05%) and 0.09% following the 1997 OMB standards.

0.4% of participants identified their ethnicity as Hispanic or Latino, following the 1997 OMB standards. Whereas 3.6% of participants identified as Hispanic according to 1977 OMB standards.

Table 28. Foreign Enrollment: Aggregate Data, NIH Foreign Research Protocols Reported in FY 2004: Percent Analysis

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

Number of Protocols with Enrollment Data: 80

	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic	White	Unknown/ Other	Total
Female	238	53,502	12,468	16,698	26,761	7,806	117,473
	0.10%	**22.28%**	**5.19%**	**6.96%**	**11.15%**	**3.25%**	**48.93%**
	0.20%	*45.54%*	*10.61%*	*14.21%*	*22.78%*	*6.64%*	*100.00%*
	54.84%	48.46%	62.00%	85.37%	35.72%	53.23%	48.93%
Male	196	56,751	4,958	2,474	48,128	6,860	119,367
	0.08%	**23.64%**	**2.07%**	**1.03%**	**20.05%**	**2.86%**	**49.72%**
	0.16%	*47.54%*	*4.15%*	*2.07%*	*40.32%*	*5.75%*	*100.00%*
	45.16%	51.40%	24.65%	12.65%	64.25%	46.77%	49.72%
Unknown	0	152	2,684	388	21	0	3,245
	0.000%	**0.06%**	**1.12%**	**0.16%**	**0.01%**	**0.00%**	**1.35%**
	0.00%	*4.68%*	*82.71%*	*11.96%*	*0.63%*	*0.00%*	*100.00%*
	0.00%	0.14%	13.35%	1.98%	0.03%	0.00%	1.35%
Total	434	110,405	20,110	19,560	74,910	14,666	240,085
	0.18%	**45.99%**	**8.38%**	**8.15%**	**31.20%**	**6.11%**	**100.00%**
	0.18%	*45.99%*	*8.38%*	*8.15%*	*31.20%*	*6.11%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 285

	Total of All Subjects by Race								Total of All Subjects by Ethnicity			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	114	1,642,680	59,350	5,751	156,114	7,126	19,190	1,890,325	1,864,422	19,010	6,893	1,890,325
	0.00%	**37.99%**	**1.37%**	**0.13%**	**3.61%**	**0.16%**	**0.44%**	**43.72%**	**43.12%**	**0.44%**	**0.16%**	**43.72%**
	0.01%	*86.90%*	*3.14%*	*0.30%*	*8.26%*	*0.38%*	*1.02%*	*100.00%*	*98.63%*	*1.01%*	*0.36%*	*100.00%*
	59.07%	42.55%	59.51%	49.98%	53.44%	50.70%	41.58%	43.72%	43.61%	53.12%	54.84%	43.72%
Male	79	2,217,569	39,215	5,754	135,622	6,919	17,702	2,422,760	2,402,313	16,517	3,930	2,422,760
	0.00%	**51.28%**	**0.91%**	**0.13%**	**3.13%**	**0.16%**	**0.41%**	**56.03%**	**55.56%**	**0.38%**	**0.09%**	**56.03%**
	0.00%	*91.53%*	*1.62%*	*0.24%*	*5.59%*	*0.29%*	0.73%	*100.00%*	*99.16%*	*0.68%*	*0.16%*	*100.00%*
	40.93%	57.45%	39.32%	50.00%	46.39%	49.22%	38.35%	56.03%	56.19%	46.15%	31.26%	56.03%
Unknown	0	10	1,163	2	506	11	9,265	10,957	8,949	261	1,747	10,957
	0.00%	**0.00%**	**0.03%**	**0.00%**	**0.01%**	**0.00%**	*0.21%*	**0.25%**	**0.21%**	**0.01%**	**0.04%**	**0.25%**
	0.00%	*0.09%*	*10.61%*	0.02%	*4.62%*	*0.10%*	*84.56%*	*100.00%*	*81.67%*	*2.38%*	*15.94%*	*100.00%*
	0.00%	0.00%	1.17%	0.02%	0.17%	0.08%	20.07%	0.25%	0.21%	0.73%	13.90%	0.25%
Total	193	3,860,259	99,728	11,507	292,142	14,056	46,157	4,324,042	4,275,684	35,788	12,570	4,324,042
	0.00%	**89.27%**	**2.31%**	**0.27%**	**6.76%**	**0.33%**	**1.07%**	**100.00%**	**98.88%**	**0.83%**	**0.29%**	**100.00%**
	0.00%	*89.27%*	*2.31%*	*0.27%*	*6.76%*	*0.33%*	*1.07%*	*100.00%*	*98.88%*	*0.83%*	*0.29%*	*100.00%*
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

SUMMARY TOTALS: Old Form + New Form							
TOTAL		TOTAL		TOTAL		OVERALL	
Females	2,007,798	Males	2,542,127	Unknown	14,202	Total	4,564,127
	43.99%		55.70%		0.31%		100%

Total Number of Protocols with Enrollment Data: 365

Table 28. Foreign Enrollment: Aggregate Data, NIH Foreign Research Protocols Reported in FY 2004: Percent Analysis

Data Table Comments:

More males (2,542,127 or 55.7%) than females (2,007,798 or 44%) are enrolled in aggregate extramural research protocols.

Largest identified racial minority group is Asian Pacific Islanders at 46% following the 1977 OMB standards and 89% following the 1997 OMB standards.

The smallest identified racial minority group is American Indian/Alaskan Native at (0.2%) following the 1977 OMB standards and 0% following the 1997 OMB standards.

0.83% of participants identified their ethnicity as Hispanic or Latino following the 1997 OMB standards. Whereas, 8% of participants identified as Hispanic according to the 1977 OMB standards.

Table 29. Summary Ethnicity Enrollment Report: Number of Hispanics or Latinos Reported in FY 2003 and FY 2004: Percent Analysis

Hispanic Ethnicity Enrollment by Sex and Race

Year	Sex/Gender	American Indian/ Alaska Native	Asian	Black or African American	White	Hawaiian/ Pacific Islander	More Than One Race	Unknown/ Other	TOTAL
2003	Female	2,902	1,326	7,949	224,153	311	14,460	127,507	378,608
	%	**0.47%**	**0.22%**	**1.30%**	**36.65%**	**0.05%**	**2.36%**	**20.85%**	**61.90%**
		0.77%	*0.35%*	*2.10%*	*59.20%*	*0.08%*	*3.82%*	*33.68%*	*100.00%*
		53.74%	67.90%	54.57%	63.96%	45.80%	51.48%	60.57%	61.90%
	Male	2,481	627	6,582	125,737	367	13,545	81,493	230,832
	%	**0.41%**	**0.10%**	**1.08%**	**20.56%**	**0.06%**	**2.21%**	**13.32%**	**37.74%**
		1.07%	*0.27%*	*2.85%*	*54.47%*	*0.16%*	*5.87%*	*35.30%*	*100.00%*
		45.94%	32.10%	45.19%	35.88%	54.05%	48.22%	38.71%	37.74%
	Unknown	17	0	35	549	1	83	1,516	2,201
	%	**0.00%**	**0.00%**	**0.01%**	**0.09%**	**0.00%**	**0.01%**	**0.25%**	**0.36%**
		0.77%	*0.00%*	*1.59%*	*24.94%*	*0.05%*	*3.77%*	*68.88%*	*100.00%*
		0.31%	0.00%	0.24%	0.16%	0.15%	0.30%	0.72%	0.36%
	TOTAL	5,400	1,953	14,566	350,439	679	28,088	210,516	611,641
	%	**0.88%**	**0.32%**	**2.38%**	**57.29%**	**0.11%**	**4.59%**	**34.42%**	**100.00%**
		0.88%	*0.32%*	*2.38%*	*57.29%*	*0.11%*	*4.59%*	*34.42%*	*100.00%*
		100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
2004	Female	3635	2777	13372	238291	951	31611	182887	473,524
	%	**0.48%**	**0.37%**	**1.77%**	**31.51%**	**0.13%**	**4.18%**	**24.18%**	**62.61%**
		0.77%	*0.59%*	*2.82%*	*50.32%*	*0.20%*	*6.68%*	*38.62%*	*100.00%*
		56.73%	55.10%	52.90%	65.99%	46.69%	50.25%	62.30%	62.61%
	Male	2683	2105	11639	119401	891	30630	109094	276,443
	%	**0.35%**	**0.28%**	**1.54%**	**15.79%**	**0.12%**	**4.05%**	**14.42%**	**36.55%**
		0.97%	*0.76%*	*4.21%*	*43.19%*	*0.32%*	*11.08%*	*39.46%*	*100.00%*
		41.87%	41.77%	46.05%	33.06%	43.74%	48.69%	37.16%	36.55%
	Unknown	90	158	265	3420	195	668	1576	6,372
	%	**0.01%**	**0.02%**	**0.04%**	**0.45%**	**0.03%**	**0.09%**	**0.21%**	**0.84%**
		1.41%	*2.48%*	*4.16%*	*53.67%*	*3.06%*	*10.48%*	*24.73%*	*100.00%*
		1.40%	3.13%	1.05%	0.95%	9.57%	1.06%	0.54%	0.84%
	TOTAL	6,408	5,040	25,276	361,112	2,037	62,909	293,557	756,339
	%	**0.85%**	**0.67%**	**3.34%**	**47.74%**	**0.27%**	**8.32%**	**38.81%**	**100.00%**
		0.85%	*0.67%*	*3.34%*	*47.74%*	*0.27%*	*8.32%*	*38.81%*	*100.00%*
		100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Number of Protocols with Enrollment Data: 6,313

Number of Protocols with Enrollment Data: 7,343

SUMMARY TOTALS: Old Form + New Form								
2003	TOTAL				TOTAL		OVERALL	
	Females	378,608		230,832	Unknown	2,201	Total	611,641
		61.90%		37.74%		0.36%		100%
2004	TOTAL				TOTAL		OVERALL	
	Females	473,524		276,443	Unknown	6,372	Total	756,339
		62.61%		36.55%		0.84%		100%

APPENDICES

Appendix A

Explanation of Sex and Minority Codes

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

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

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

Appendix B

NIH Tracking and Inclusion Committee Members

- Full Committee

NIH Tracking and Inclusion Committee
2005 List of Members

Office of the Director

Office of Research on Women's Health
Vivian Pinn (Co-Chair), Angela Bates, Lisa Begg, Joyce Rudick

Office of Extramural Research
Carlos Caban*, Viktoriya Anufriyeva, Maria Koshy

Office of Acquisition, Management and Procurement
Barbara Levy

National Cancer Institute
Margaret Holmes*, Marilyn Gaston, Kim Witherspoon, Lisa Krueger, Clarissa Douglass

National Eye Institute
Lore Anne McNicol*, William Darby, Donald Everett

National Heart, Lung, and Blood Institute
Carl Roth (Co-Chair)*, Sharry Palagi, Barbara Liu

National Human Genome Research Institute
Bettie Graham*, Pam Sellman

National Institute on Aging
Miriam Kelty *, Karen Bashir, Kate Nagy

National Institute on Alcohol Abuse and Alcoholism
Dorita Sewell*, Carmen Richardson

National Institute of Allergy and Infectious Diseases
Diane Adger-Johnson*, Susan Schafer, Diane Yerg, Martin Gutierrez

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Madeline Turkeltaub*, Charisse Lamar

National Institute of Child Health and Human Development
Eugene Hayunga*, Sandi Delcore

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

List of Members, continued...

National Institute on Deafness and Other Communication Disorders
Julie Gulya*, Lana Shekim

National Institute of Dental and Craniofacial Research
Richard Mowery *, Trenita Davis

National Institute of Diabetes, Digestive and Kidney Disorders
Patricia Robuck*, Lauren Meskill, Donna James

National Institute on Drug Addiction
Christie Baxter*

National Institute of Environmental Health Sciences
Martha Barnes *

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

National Institute of Mental Health
Catherine Roca *, Pamela Wexler, Sue Kennel, Ernesto Marquez, Dawn Corbett

National Institute of Neurological Disorders and Stroke
Frances Yee *, Kristy Woolbert

National Institute of Nursing Research
Alexis Bakos *, Christine Shaw

National Library of Medicine
Dwight Mowery *

Warren G. Magnuson Clinical Center
Kim Jarema *, Dee Koziol

National Center for Complementary and Alternative Medicine
April Bowers *

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

List of Members, continued...

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

Fogarty International Center
Aron Primack*

Center for Scientific Review
Anita Miller Sostek*

Office of Intramural Research
Alan Sandler*

National Center for Minority Health and Health Disparaties
Ivy Chan*

National Institute of Biomedical Imaging and Bioengineering
Meredith Temple-O Connor*, Tinera Fobbs, Tony Demsey, Casey Goode

Division of Extramural Activities Support
Mary Lou Prince*, Dorothy Sanders

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

Appendix C

Internet Homepage:

Inclusion of Women and Minorities Policy Implementation

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

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

Inclusion of Women and Minorities Policy Implementation

Current Policy Documents and References:

- **10/09/2001 NIH Guide Notice** - The NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research was amended October 2001. Click here for a complete copy of the Amended Policy that provides full explanation of the October 2001 policy notice.
- **08/08/2001 NIH Guide Notice** - NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research. This notice provides additional guidance and instruction for using the revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity found in the PHS 398 (rev. 5/01) and PHS 2590 (rev. 5/01) instructions and forms.
- **Inclusion Table (07/25/2001)** - Prior format for reporting sex/gender and race/ethnicity data using the 1977 OMB standards for the classification of federal data on race and ethnicity. This format is superceded by the Target/Planned Enrollment Table and Inclusion Enrollment Reports that use the 1997 OBM standards for the classification of federal data on race and ethnicity.
- **Women's Inclusion as Participants in Research** - Page from the Office of Research on Women's Health (ORWH) Web site.
- **Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research** - To help investigators to understand and comply with the NIH's inclusion policies, the ORWH collaborated in the preparation and publication of this Notebook, available here in Adobe Acrobat (PDF) format. This publication contains two appendices. Appendix A summarizes the inclusion guidelines; Appendix B contains sample questions and answers to assist investigators in preparing their applications in accordance with the inclusion guidelines.

OUTREACH NOTEBOOK (Pages 1-39 of PDF file)
INCLUSION GUIDELINES (Pages 40-51 of PDF file)
QUESTIONS AND ANSWERS (Pages 52-87 of PDF file)

Historical Documents and References:

- **08/02/2000 NIH Guide Notice** - NIH Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research - Updated August 2, 2000. Changes to the Guidelines, Sections 'III.B. NIH Phase III Clinical Trials' and 'V. Definitions' are highlighted in bold type.
- **NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Updated August 2, 2000** - A complete text of the Updated Guidelines, with changes to the Guidelines, Sections 'III.B. NIH Phase III Clinical Trials' and 'V. Definitions' highlighted in bold type. The list of NIH Contacts has also been updated.
- **03/18/1994 NIH Guide Notice** - NIH Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research.

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

Appendix D

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

(Amended, October, 2001)

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

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

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

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

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

I. LEGISLATIVE BACKGROUND

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

The statute states that:

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

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

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

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

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

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

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

The statute speaks specifically to outreach and states that:

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

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

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

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

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

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

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

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

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

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

II. POLICY

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

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

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

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

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

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

1. Prior Studies Support the Existence of Significant Differences

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

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

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

2. Prior Studies Support No Significant Differences

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

3. Prior Studies Neither Support nor Negate Significant Differences

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

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

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

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

III. ROLES AND RESPONSIBILITIES

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

1. NIH Staff

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

2. Principal Investigators

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

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

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

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

3. Institutional Review Boards (IRBs)

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

4. Peer Review Groups

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

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

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

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

Or contact:

National Institutes of HealthDivision of Acquisition Policy and EvaluationOffice of Acquisition Management and Policy6100 Executive Boulevard, Room 6C01Phone: 301-496-6014Fax: 301-402-1199

5. NIH Advisory Councils

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

6. Institute/Center Directors

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

7. NIH Director

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

IV. DEFINITIONS

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

A. Clinical Research

Clinical research is defined as:

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

B. NIH-defined Clinical Trial

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

C. Valid Analysis

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

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

D. Significant Difference

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

E. Racial and Ethnic Categories

1. Minority Groups

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

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

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

The following definitions apply for ethnic categories.

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

Not Hispanic or Latino

The following definitions apply for racial categories.

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

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

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

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

2. Majority Group

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

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

3. Subpopulations

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

F. Outreach Strategies

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

V. NIH CONTACTS FOR MORE INFORMATION

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

Dr. Marvin Kalt
National Cancer Institute
Executive Plaza North
6116 Executive Boulevard, Suite 8001
Bethesda, MD 20892
Telephone: (301) 496-5147
Email: kaltm@dea.nci.nih.gov

Dr. Lore Anne McNicol
National Eye Institute
Executive Plaza South
6120 Executive Boulevard, Room 350
Rockville, MD 20892
Telephone: (301) 496-5301
Email: loreanne.mcnicol@nei.nih.gov

Ms. Sharry Palagi
National Heart, Lung and Blood Institute
Building 31
31 Center Drive, Room 5A-07
Bethesda, MD 20892
Telephone: (301) 402-3424
Email: palagis@nih.gov

Dr. Miriam Kelty
National Institute on Aging
Gateway Building
7201 Wisconsin Avenue, Room 2C218
Bethesda, MD 20892
Telephone: (301) 496-9322
Email: keltyM@nia.nih.gov

Dr. Lorraine Gunzerath
National Institute on Alcohol Abuse and Alcoholism
Willco Building
6000 Executive Boulevard, Suite 409
Rockville, MD 20892
Telephone: (301) 443-2369
Email: lgunzera@mail.nih.gov

Dr. John McGowan
National Institute of Allergy and Infectious Diseases
6700 B Rockledge 6700 Rockledge Drive
Bethesda, MD 20817
Telephone: (301) 496-7291
Email: jm80c@nih.gov

Madeline Turkeltaub RN, Ph.D., CRNP, FAAN
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd., Suite 800 MSC 4872
Rockville, MD 20857
Telephone: (301) 451-5888
Email: MTurkeltaub@mail.nih.gov

Dr. Susan Streufert
National Institute of Child Health and Human Development
6100 Executive Boulevard
Building 61EB, Room 4A05
Bethesda, MD 20892
Telephone: (301) 435-6856
Email: streufes@mail.nih.gov

Dr. Lana Shekim
National Institute on Deafness and Other Communication Disorders
Executive Plaza South
6120 Executive Boulevard, Room 400C
Rockville, MD 20892
Telephone: (301) 496-5061
Email: ShekimL@nidcd.nih.gov

Richard Mowery, Ph.D.
National Institute on Dental and Craniofacial Research
Natcher Building
Building 45, Room 4AS543F MSC 6401
Bethesda, MD 20892
Telephone: (301) 594-4848
Email: mowerich@mail.nih.gov

Patricia Robuck Ph.D., MPH
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Blvd., Room 659
Bethesda, MD 20817
Telephone: (301) 480-8300
Email: pr132q@nih.gov

Dr. Teresa Levitin
National Institute on Drug Abuse
Neuroscience Building
6001 Executive Boulevard, Room 3158
Bethesda, MD 20852
Telephone: (301) 443-2755
Email: tlevitin@nida.nih.gov

Dr. Anne P. Sassaman
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-30
Research Triangle Park, NC 27709
Telephone: (919) 541-7723
Email: sassaman@niehs.nih.go

Dr. Alison Cole
National Institute of General Medical Sciences
Natcher Building
Building 45, Room 2AS49K
Bethesda, MD 20892
Telephone: (301) 594-1826
Email: colea@nigms.nih.gov

Catherine Roca, M.D.
National Institute of Mental Health
Neuroscience Building
6001 Executive Boulevard, Room 8125
Bethesda, MD 20852
Telephone: (301) 443-3488
Email: rocac@mail.nih.gov

Dr. Frances Yee, Ph.D.
National Institute of Neurological Disorders and Stroke
Neuroscience Building
6001 Executive Boulevard, Room 2227 MSC 9520
Bethesda, MD 20852-9520
Telephone: (301) 496-5447
Email: yeef@ninds.nih.gov

Bettie Graham, Ph.D.
National Human Genome Research Institute
5635 Fishers Lane, Suite 4073 MSC 9305
Rockville, MD 20852
Telephone: (301) 496-7531
Email: bettie_graham@mail.nih.gov

Barbara Smothers, Ph.D.
National Institute of Nursing Research
6701 Democracy Blvd., Suite 710, MSC 4870
Bethesda, MD 20892
Telephone: (301) 594-5976
Email: bs86h@nih.gov

Jonathon Berman, M.D., Ph.D., FAAP
National Center for Complementary and Alternative Medicine
6707 Democracy Blvd., Suite 401
Bethesda, MD, 20892
Telephone: (301) 594-7105
Email: bermanjo@mail.nih.gov

Shelia McClure, Ph.D.
National Center for Research Resources
6701 Democracy Blvd., Room 932, MSC 4874
Bethesda, MD 20892-4874
Telephone: (301) 4451-6536
Email: mcclursh@mail.nih.gov

Dr. Kenneth Bridbord
Fogarty International Center
Building 31
31 Center Drive, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-2516
Email: bridbordk@ficod.fic.nih.gov

Anthony Demsey, Ph.D.
National Institute of Biomedical Imaging and Bioengineering
Two Democracy Boulevard, Suite 240
Bethesda, MD 20892
Telephone: (301) 402-7039
Email: demseya@mail.nih.gov

Derrick Tabor, Ph.D.
National Center for Minority Health and Health Disparities
2 Democracy Boulevard, Suite 800
Bethesda, MD 20817
Telephone: (301) 402-1366
Email: tabord@mail.nih.gov

Appendix E

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

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

Release Date: August 8, 2001

NOTICE: NOT-OD-01-053

National Institutes of Health

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

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

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

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

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

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

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

Ethnic Categories:

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

Not Hispanic or Latino

Racial Categories:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Annual Progress Reports (type 5) and Competing Supplement Applications

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

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

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

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

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

III. Frequently Asked Questions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Marvin Kalt
National Cancer Institute
Executive Plaza North
6116 Executive Boulevard, Suite 8001
Bethesda, MD 20892
Telephone: (301) 496-5147
Email: kaltm@dea.nci.nih.gov

Dr. Lore Anne McNicol
National Eye Institute
Executive Plaza South
6120 Executive Boulevard, Room 350
Rockville, MD 20892
Telephone: (301) 496-5301
Email: loreanne.mcnicol@nei.nih.gov

Ms. Sharry Palagi
National Heart, Lung and Blood Institute
Building 31
31 Center Drive, Room 5A-07
Bethesda, MD 20892
Telephone: (301) 402-3424
Email: palagis@nih.gov

Dr. Miriam Kelty
National Institute on Aging
Gateway Building
7201 Wisconsin Avenue, Room 2C218
Bethesda, MD 20892
Telephone: (301) 496-9322
Email: keltyM@nia.nih.gov

Dr. Lorraine Gunzerath
National Institute on Alcohol Abuse and Alcoholism
Willco Building
6000 Executive Boulevard, Suite 409
Rockville, MD 20892
Telephone: (301) 443-2369
Email: lgunzera@mail.nih.gov

Dr. John McGowan
National Institute of Allergy and Infectious Diseases
6700 B Rockledge 6700 Rockledge Drive
Bethesda, MD 20817
Telephone: (301) 496-7291

Email: jm80c@nih.gov

Madeline Turkeltaub RN, Ph.D., CRNP, FAAN
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd., Suite 800 MSC 4872
Rockville, MD 20857
Telephone: (301) 451-5888
Email: MTurkeltaub@mail.nih.gov

Dr. Susan Streufert
National Institute of Child Health and Human Development
6100 Executive Boulevard
Building 61EB, Room 4A05
Bethesda, MD 20892
Telephone: (301) 435-6856
Email: streufes@mail.nih.gov

Dr. Lana Shekim
National Institute on Deafness and Other Communication Disorders
Executive Plaza South
6120 Executive Boulevard, Room 400C
Rockville, MD 20892
Telephone: (301) 496-5061
Email: ShekimL@nidcd.nih.gov

Richard Mowery, Ph.D.
National Institute on Dental and Craniofacial Research
Natcher Building
Building 45, Room 4AS543F MSC 6401
Bethesda, MD 20892
Telephone: (301) 594-4848
Email: mowerich@mail.nih.gov

Patricia Robuck Ph.D., MPH
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Blvd., Room 659
Bethesda, MD 20817
Telephone: (301) 480-8300
Email: pr132q@nih.gov

Dr. Teresa Levitin
National Institute on Drug Abuse
Neuroscience Building
6001 Executive Boulevard, Room 3158
Bethesda, MD 20852
Telephone: (301) 443-2755
Email: tlevitin@nida.nih.gov

Dr. Anne P. Sassaman
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-30
Research Triangle Park, NC 27709
Telephone: (919) 541-7723
Email: sassaman@niehs.nih.go

Dr. Alison Cole
National Institute of General Medical Sciences
Natcher Building
Building 45, Room 2AS49K
Bethesda, MD 20892
Telephone: (301) 594-1826
Email: colea@nigms.nih.gov

Catherine Roca, M.D.
National Institute of Mental Health
Neuroscience Building
6001 Executive Boulevard, Room 8125
Bethesda, MD 20852
Telephone: (301) 443-3488
Email: rocac@mail.nih.gov

Dr. Frances Yee, Ph.D.
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Neuroscience Building
6001 Executive Boulevard, Room 2227 MSC 9520
Bethesda, MD 20852-9520
Telephone: (301) 496-5447
Email: yeef@ninds.nih.gov

Bettie Graham, Ph.D.
National Human Genome Research Institute
5635 Fishers Lane, Suite 4073 MSC 9305
Rockville, MD 20852
Telephone: (301) 496-7531
Email: grahambj@mail.nih.gov

Barbara Smothers, Ph.D.
National Institute of Nursing Research
6701 Democracy Blvd., Suite 710, MSC 4870
Bethesda, MD 20892
Telephone: (301) 594-5976
Email: bs86h@nih.gov

Jonathon Berman, M.D., Ph.D., FAAP
National Center for Complementary and Alternative Medicine
6707 Democracy Blvd., Suite 401
Bethesda, MD, 20892

Telephone: (301) 594-7105
Email: bermanjo@mail.nih.gov

Shelia McClure, Ph.D.
National Center for Research Resources
6701 Democracy Blvd., Room 932, MSC 4874
Bethesda, MD 20892-4874
Telephone: (301) 4451-6536
Email: mcclursh@mail.nih.gov

Dr. Kenneth Bridbord
Fogarty International Center
Building 31
31 Center Drive, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-2516
Email: bridbordk@ficod.fic.nih.gov

Anthony Demsey, Ph.D.
National Institute of Biomedical Imaging and Bioengineering
Two Democracy Boulevard, Suite 240
Bethesda, MD 20892
Telephone: (301) 402-7039
Email: demseya@mail.nih.gov

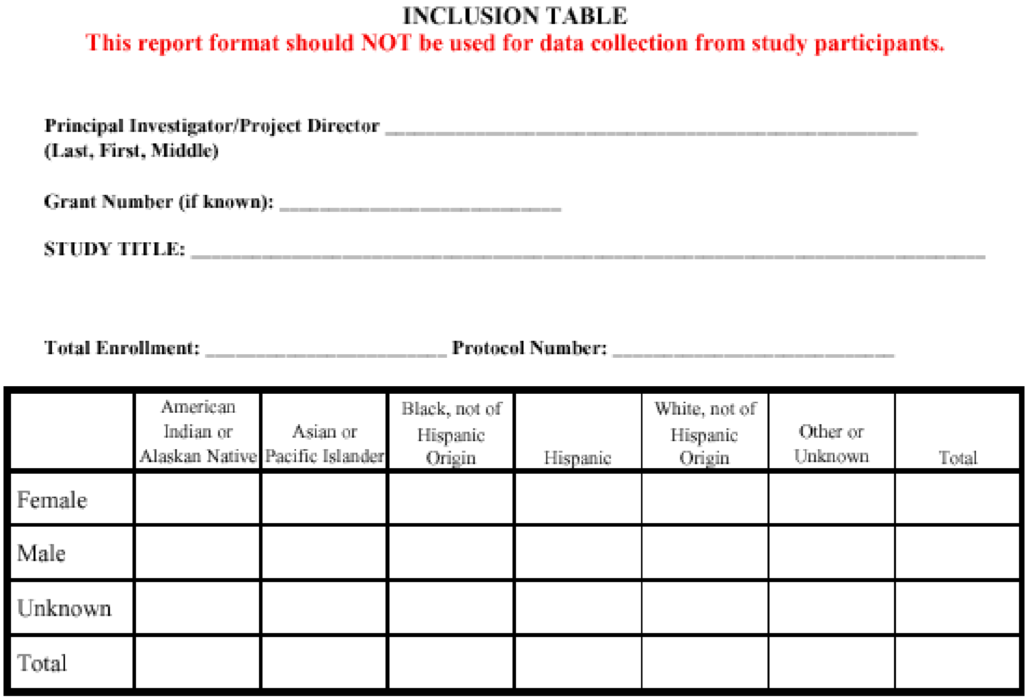
Derrick Tabor, Ph.D.
National Center for Minority Health and Health Disparities
2 Democracy Boulevard, Suite 800
Bethesda, MD 20817
Telephone: (301) 402-1366
Email: tabord@mail.nih.gov

APPENDIX F

NIH Inclusion Tables for Target and Enrollment Data

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

Old Table for Target & Enrollment Data Collection



INCLUSION TABLE

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

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

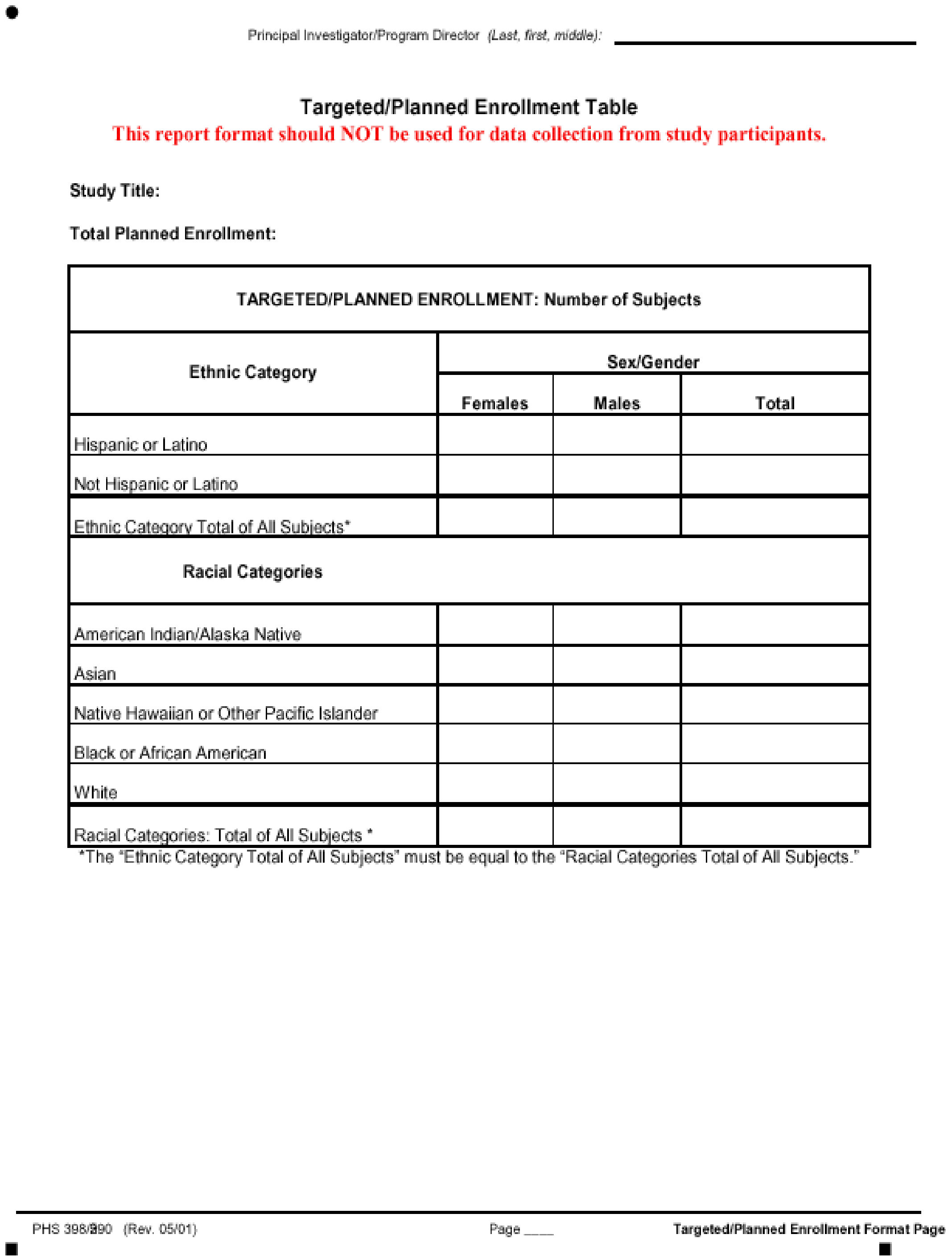
Grant Number (if known): ________________________

STUDY TITLE: ____

Total Enrollment: _____________________ **Protocol Number:** ________________________

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

New Table for Target Data Collection



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

Targeted/Planned Enrollment Table

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

Study Title:

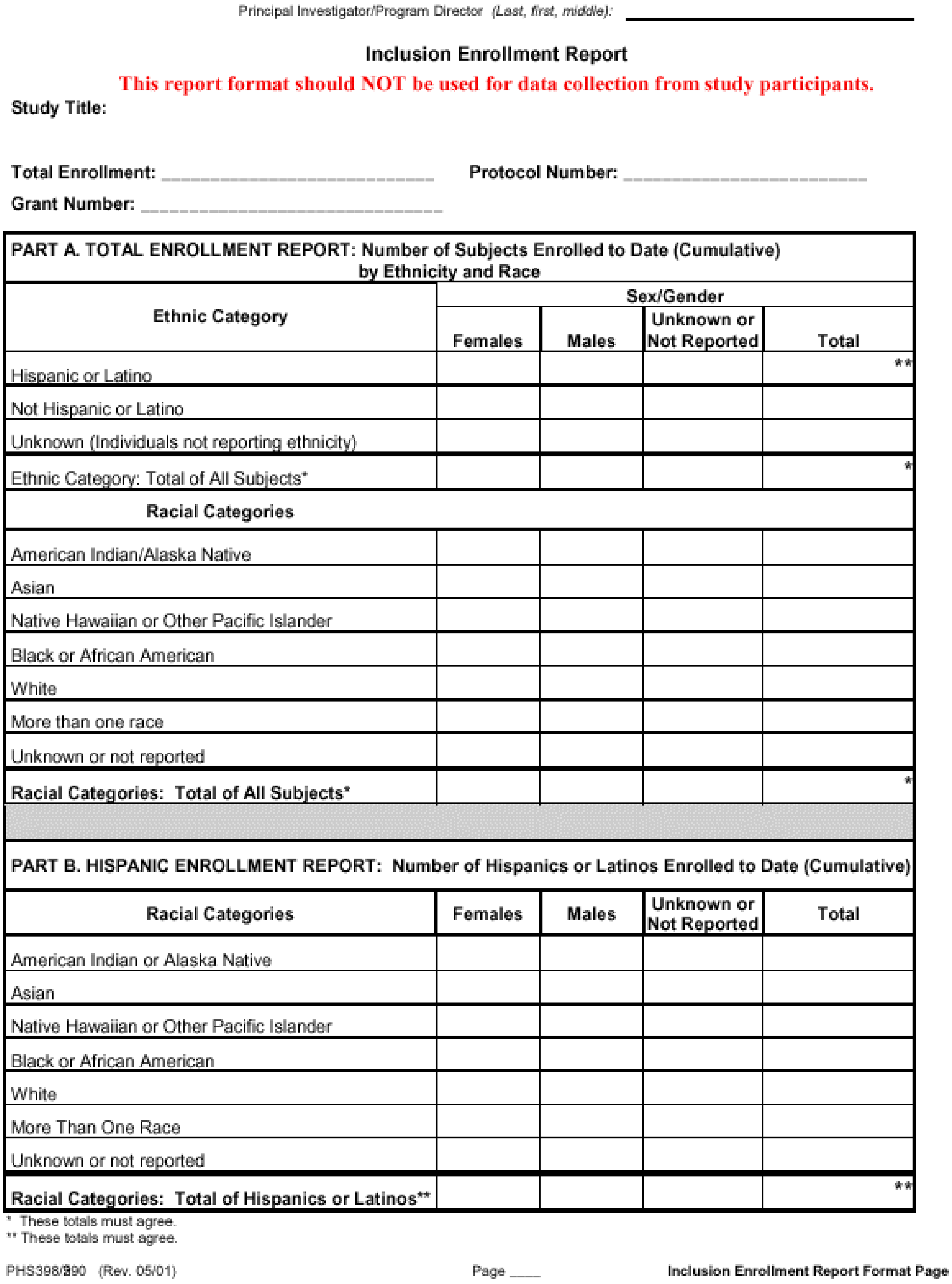
Total Planned Enrollment:

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

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

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

New Table for Enrollment Data Collection

- 

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

Inclusion Enrollment Report

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

Study Title:

Total Enrollment: ____________________ **Protocol Number:** ____________________

Grant Number: ____________________

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

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

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

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

* These totals must agree.

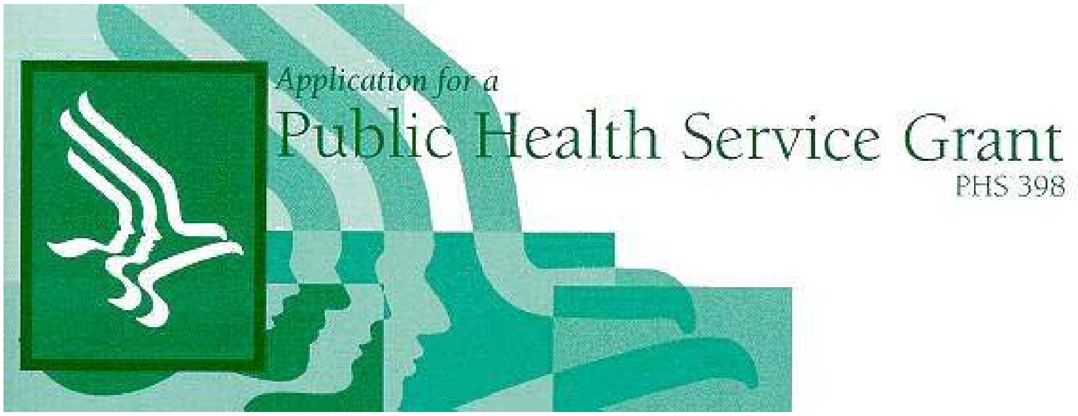
** These totals must agree.

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

Appendix G

Updates to PHS398

Competing - Public Health Service Grant Application



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Grant Application
PHS 398 (Revised 9/2004)

See the *11/2/2004 NIH Guide Notice* for important changes to this version.

All notable changes made to PHS 398 form pages are listed at the *bottom of this page* (Updated 3/16/2005).

Downloadable Instructions and Form Files

Some of the MS Word and PDF files are large and may take a few minutes to download.

PHS 398 Instructions

This edition of the PHS 398 has been reorganized into three distinct parts, each of which is available as a separate file in the MS Word and PDF versions. Principal investigators and institutions will need to use all three parts of the instructions in order to prepare a complete and acceptable application.

PHS 398 Instructions Files - Part I, II, and III			
Part I, Instructions	MS Word	PDF	Flash or HTML
Part II, Human Subjects Research Supplement	MS Word	PDF	

Part III, Policy, Assurances, Definitions	MS Word	PDF	

If the links between the three parts do not function properly when using the MS Word and PDF versions of these instructions, save the three files to your hard drive (see Saving Files Locally), rather than opening them in your browser. Be sure that the three files are saved to the same folder/directory.

PHS 398 Fillable Forms

The links below allow for downloading of individual and combined form files in MS Word and PDF formats. Please see the Adobe Acrobat or PDF Forms section of the "Help Downloading Files" page for information on using the fillable PDF forms.

Fillable Individual PHS 398 Forms		
Form Page 1: Face Page	MS Word	PDF
Form Page 2: Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells	MS Word	PDF
Form Page 3: Research Grant Table of Contents	MS Word	PDF
Form Page 4: Detailed Budget for Initial Budget Period	MS Word	PDF
Form Page 5: Budget for Entire Proposed Period of Support	MS Word	PDF
Modular Budget Format Page	MS Word	PDF
Modular Budget **Sample**: Same Modules	MS Word	PDF
Modular Budget **Sample**: Variable Modules	MS Word	PDF
Biographical Sketch Format Page	MS Word	PDF
Biographical Sketch **Sample**	MS Word	PDF
Resources Format Page	MS Word	PDF
Checklist Form Page	MS Word	PDF
Personal Data Form Page	MS Word	PDF
Continuation Page	MS Word	PDF
Targeted/Planned Enrollment Table Format Page	MS Word	PDF
Inclusion Enrollment Report Format Page	MS Word	PDF
Mailing Address and RFA Labels	MS Word	PDF
Other Support Format Page: Example	MS Word	PDF
Personnel Report Format Page	MS Word	PDF
Fillable Research Career Development		

Award Forms		
Substitute Form Page 3: Research Career Development Award Table of Contents	MS Word	PDF
Research Career Development Award Reference Guidelines	MS Word	PDF
Fillable Institutional National Research Service Award (NRSA) Forms		
Substitute Table of Contents for Institutional NRSA	MS Word	PDF
Substitute Detailed Budget for Initial Budget Period Direct Costs	MS Word	PDF
Substitute Budget for Entire Proposed Period of Support Direct Costs	MS Word	PDF
Research (SBIR)/ Small Business Technology Transfer (STTR) Forms		
Full Set of SBIR and STTR Forms (Phase I and Phase II) *Does NOT include Continuation Page, Biographical Sketch, or any Sample pages, all of which may be downloaded below.*	MS Word	PDF
STTR Research Institution Budget Form Page	MS Word	PDF
Continuation Page	MS Word	PDF
Biographical Sketch Format Page	MS Word	PDF
Biographical Sketch **Sample**	MS Word	PDF
Budget **Sample - SBIR** (STTR Under Development)	MS Word	PDF
Combined PHS 398 Forms File *Does NOT include the Biographical Sketch page, Continuation Page, or any of the Sample/Example pages (Biosketch Sample, Other Support Sample). See Individual Form file links above.*	Combined PHS 398 Form Files (MS Word)	Combined PHS 398 Form Files (PDF)

For Questions Related to:

- **Application Procedures/Forms Submission:** contact GrantsInfo at grantsinfo@nih.gov or 301-435-0714.
- **Technical Problems With Forms:** visit the PHS Forms Help Desk,Technical FAQs at http://www.peacetech.com/phsforms.

Note: Other software packages for completing these applications may be available from other sources; however, it is essential that the type size and format specifications are met. Otherwise, application processing may be delayed, or the application may be returned to the applicant without review.

Disclaimer: Reference to these software packages neither constitutes nor should be inferred to be an endorsement or recommendation of any product, service, or enterprise by the National Institutes of Health, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

Notable Changes Made to PHS 398

- Revisions have been made in the PHS 398 to specify additional acceptable font typefaces (Arial, Helvetica, Palatino Linotype or Georgia are now acceptable); to provide clearer budget guidance for applications that include consortium F&A costs; and to clarify format requirements for Appendix material (Appendix material may be two-sided). See the NIH Guide Notice for details regarding revisions made. Minor formatting revisions have been made to some form pages to improve usability (3/16/05).
- Revisions have been made in the PHS 398, Part II, Human Subjects Research Supplement, to further address NIH implementation of OHRP Guidance on research involving coded private information or biological specimens. Notable changes in content have been marked in purple. Minor revisions and formatting changes have been made in the PHS 398, Parts I and III (1/20/05).
- Chapter V of the PHS 398 has been revised to reflect that the modular budget format no longer applies to SBIR/STTR grant applications (1/14/05).
- Significant revisions have been made in the PHS 398, Part II, Human Subjects Research Supplement, to address NIH implementation of OHRP Guidance on research involving coded private information or biological specimens. Notable changes in content have been marked in purple. Minor revisions and formatting changes have been made in the PHS 398, Parts I and III. On Form Page 3, Research Grant Table of Contents, the ordering of items in the Research Plan has been revised (12/30/04).
- Page numbering on Form Page 2 and Form Page 2-continued has been changed to Page 2 and Page 3. Be sure to number all pages in application sequentially (11/23/04).
- Clarification of font and format specifications (11/17/04).
- New PHS 398 (Rev. 9/04) instructions and forms posted 11/02/2004. See the 11/2/2004 NIH Guide Notice for important details regarding changes made to this version.

Revised PHS 398 (DHHS Public Health Service Grant Application) Now Available

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Notice Number: NOT-OD-05-006

Key Dates
Release Date: November 02, 2004

Issued by
National Institutes of Health (NIH), (http://www.nih.gov/)

EFFECTIVE DATE: The newly revised "Application for a DHHS Public Health Service Grant" (PHS 398, rev. 9/04) instructions and forms are now available and will be accepted for submission/receipt dates on or after December 1, 2004. All applications received on or after May 10, 2005 **must** use the new instructions and forms. During the transition period, applications using the previous version (rev. 5/01) of the PHS 398 will be accepted through May 9, 2005. However, after this date, applications submitted using instructions and forms other than the PHS 398 (rev 9/04) will be returned to the applicant.

The newly revised instructions and forms are available at http://grants.nih.gov/grants/forms.htm. The forms available on the website continue to be provided in two formats—MS Word and PDF-fillable using Adobe Acrobat Reader Software. Free Adobe Software may be accessed at http://www.adobe.com/products/acrobat/readstep.html. Applicants are strongly encouraged to access the instructions and forms via the Internet because they provide valuable links to current policy documents and allow easy navigation of the instructions. This is particularly important with this version due to the interactive format of the instructions. For further information, contact GrantsInfo@nih.gov.

SBIR/STTR applicants who are preparing an application for the December 1, 2004 submission date may use the previous PHS 398 version (rev. 05/01) in accordance with instructions in Chapter IV of the PHS 2004-2 Omnibus SBIR/STTR Grant Solicitation. However, applicants who wish to use the new forms should use the following set of instructions (MS Word / PDF). in accordance with instructions in Chapter IV of the PHS 2004-2 Omnibus SBIR/STTR Grant Solicitation. The PHS 2005-2 Omnibus Solicitation, with updated instructions, will be released on or around January 14, 2005.

As in the past, applicants should read the instructions carefully. The following is a list of notable changes.

Notable Changes to the PHS 398 (rev. 9/04):

This edition of the PHS 398 has been *extensively* rewritten with a focus on clarity and special emphasis on simplicity and plain language.

Overall Format Changes

The format has been organized into three distinct, but integrally linked, parts:

- **Part I:** Instructions for Preparing the Application
  - Efforts have been made to include only instructional material related to the preparation, submission and review of your application.
  - When applicable, instructions have been revised to incorporate appropriate policy changes. However, detailed information pertaining to policies, assurances, definitions and other information is now found in Part III: Policies, Assurances, Definitions and Other Information.

- **Part II:** Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan
  - This section includes instructions for preparing the human subjects section of the research plan (Section e) and related policies related to Human Subjects Research.
  - This section is also organized in a question/answer format to guide application writers through the decision making process regarding the involvement of human subjects in the proposed research.

- **Part III:** Policies, Assurances, Definitions and Other Information
  - This section contains non-instructional information relating to policies and assurances, incorporates all policy changes since the last (5/01) PHS398 revision, and includes links from Part I ("Instructions") as necessary.
  - Definitions have been harmonized with those used in the NIH Grants Policy Statement .
  - This section also includes a description of various grant mechanisms that NIH uses to fund research

Changes of Note to Specific PHS 398 Form/Format Pages:

Face Page:

- Title—Form field length has been increased to 81 characters
- eRA Commons User Name field has been added. This data item is currently optional
- Human Subjects Research box has been modified to include a new data element for Clinical Trials.
- The IPF option data field in block 9 has been eliminated

Form Page 2:

- Now 2 pages (Form Page 2 & Form Page 2-continued with 5 distinct sections—Description, Performance Sites, Key Personnel, Other Significant Contributors, and Stem Cells.

- Description/Abstract : Instructions have been added requiring the PI to succinctly (2-3 sentences) describe the relevance of the proposed research to public health. Plain language is suggested.
- Key Personnel Section : A field has been added for the eRA Commons User Name. This new data item is currently optional.
- Other Significant Contributors: This is a new field that allows the PI to identify individuals who have committed to contribute to the scientific development or execution of the project but are *not* committing any specified measurable effort. (Biographical sketches will be required for these individuals; Other Support information will not be required.)
- Human Embryonic Stem Cells: Previously embedded in the Description, information pertaining to projects that involve human embryonic stem cells has now been requested as a separate form field. A link to the Human Embryonic Stem Cell Registry is provided.

Form Pages 4 and 5: Budget pages have been modified to implement the broader application of the policy on Direct Cost Limitations (e.g., excluding consortium/contractual F&A costs when determining eligibility for any application with a direct cost limitation.) Specifically, the “Consortium/Contractual Direct Costs” budget row has been moved to above the “Subtotal Direct Costs” line. Instructions have been revised to implement the new policy.

Modular Budget Format Page : The budget data fields have been modified to implement the new policy on Direct Cost Limitations. Specifically, users must now separate the Consortium F&A costs from the other Direct Costs. Instructions have also been revised to implement the new policy.

Biographical Sketch Format Page : A field has been added for the eRA Commons User Name. This data item is currently optional.

Personal Data Page: Applicants are now requested to provide only the last four digits of the Social Security Number. While providing this information remains voluntary, it is hoped that by limiting the data to only the last four digits, individuals will be more receptive to providing it. This vital information continues provide the agency with accurate identification, referral, and review of applications and for management of PHS grant programs.

Key Personnel Report Format Page: The request for a Social Security Number is now limited to the last four digits.

Checklist Form Page:

- A field has been added for “Change in Grantee Institution”.
- Foreign Application: Two distinct options are now provided 1) Grants at Foreign Institutions or 2) Domestic Grants with Significant Foreign Involvement. This data area also includes a text entry section to list countries involved.

Specific Changes of Note to the PHS398 Instructions

- The Foreword now contains general information about the NIH Extramural Research and Research Training Programs, including useful “Quick References”, contacts within HHS and guidance for “whom to contact when.”
- Font Size Requirement: NIH now **requires** the use of Arial-11 or Helvetica-11 point font.
- NIH Peer Review Criteria have been updated to better accommodate interdisciplinary, translational, and clinical projects.
- Instructions for Modular and Non-Modular Budgets and have been revised to implement the new policy on Direct Cost Limitations; e.g., excluding consortium/contractual F&A costs when determining eligibility for any application with a direct cost limitation.
- Research Plan instructions now include a distinct section on Resource Sharing.
- Research Career Development Award Instructions:

    - Added clarifying instructions for completing sections of Form Page 2
    - Changed requirement in Career Award Instructions for Checklist Page. This page is now required at time of submission.

- Institutional Training Grant Instructions: Added clarifying instructions for completing sections of Form Page 2
- SBIR/STTR Instructions: Clarification has been added on the preparation of the Final Progress Report.

Inquiries on any changes to the forms and instructions may be directed to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
National Institutes of Health
6705 Rockledge Drive, Suite 350
Bethesda, MD 20892
Telephone: (301) 435-0938
FAX: (301) 435-3059
Email: GrantsPolicy@od.nih.gov

Updated Instructions to the PHS 398 (DHHS Public Health Service Grant Applications) Now Available

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