National Institutes of Health
Department of Health and Human Services

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

Comprehensive Report
(Fiscal Year 1999 & 2000 Tracking Data)

Blue Report

NIH Tracking/Inclusion Committee
Vivian W. Pinn, M.D., Co-Chair
Office of Research on Women's Health

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

Angela C. Bates
Office of Research on Women's Health

Larry Fanning
Office of Extramural Research
Systems Quality Assurance Interface Branch

December 2002

TABLE OF CONTENTS

Page

Part I - Comprehensive Report

Background and Current Activities

Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research……………………………………………………….1

Aggregate Data Tables

Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review.. 11-12
Table B. Extramural Research Awards: Bars to Funding and Resolutions... 13-14
Table C. Inclusion by Sex in All Research Studies Active and Funded in FY1999 and FY2000.. 15-17

Table 1. Aggregate Enrollment Data for All Extramural Research Protocols Funded in Fy1999....... 19-20
Table 2. Aggregate Enrollment Data for All Extramural Research Protocols Funded in FY2000...... 19-20
Table 3. Aggregate Enrollment Data for All Extramural Research Protocols Excluding Male-only & Female-only Protocols Funded in FY1999.......................... 21-22
Table 4. Aggregate Enrollment Data for All Extramural Research Protocols Excluding Male-only & Female-only Protocols Funded in FY2000.......................... 21-22
Table 5. Aggregate Enrollment Data for Extramural Phase III Protocols Funded in FY1999.. 23-24
Table 6. Aggregate Enrollment Data for Extramural Phase III Protocols Funded in FY2000.. 23-24
Table 7. Aggregate Enrollment Data for Phase III Research Protocols Excluding Male-only & Female-only Protocols Funded in FY1999.......................... 25-26
Table 8. Aggregate Enrollment Data for Phase III Research Protocols Excluding Male-only & Female-only Protocols Funded in FY2000.......................... 25-26
Table 9. Aggregate Enrollment Data for Intramural Research Protocols Conducted On-site and Off-site in FY 1999... 27-28
Table 10. Aggregate Enrollment Data for Intramural Research Protocols Conducted On-site and Off-site in FY2000.. 27-28
Table 11. Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-only & Female-only Protocols Funded in FY2000................................29
Table 12. Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2000..29

Summary Report of FY2000 and FY1999 Enrollment Data by Institute and Centers.......................... 31-47

TABLE OF CONTENTS (continued)

Page

Appendices

Appendix A

Explanation of Gender/Minority Codes 49

Appendix B

2002 Tracking/Inclusion Committee Membership Lists 53

Appendix C

Responses to the General Accounting Office (GAO) Report: "Women's Health: NIH Has Increased Its Efforts To Include Women in Research" GAO/HEHS-00-96, September 2002 57

Appendix D

Homepage: Inclusion of Women and Minorities Policy Implementation 65

Appendix E

NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001 69

Appendix F

NIH Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research 85

Appendix G

NIH Inclusion Tables for Target and Enrollment Data 97

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

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

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 concludes 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 F)

    - 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. Since August 2000, several training initiatives have been 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 in October 2000. This symposium focused on the updated human subjects policy and the way in which it would be implemented. The training session included a question and answer session that provided an opportunity to emphasize the importance of the policy and the importance of reviewer evaluation of the changes related to valid analyses in Phase III clinical trials. About 450 were in attendance, 400 viewed the session at satellite centers and another 175 participated through videocast. The 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. Several hundred additional extramural and intramural researchers were trained. The inclusion of human subjects in clinical research studies was included among the topics addressed during the session. The training materials may be found at the following web address: http://odoerdb2.od.nih.gov/oer/training/esa/grants_policy_update/esa_grants_policy_update.htm.

- In December 2000, the NIH Tracking and Inclusion Committee held a training session for all NIH program and grants management staff to discuss with members of the technical team, data entry and collection issues regarding the current population tracking system and IMPAC II as well as offer suggestions for the development of the new population tracking module.

- In July 2001, NIH issued the newly revised Applications for a DHHS Public Health Service Grant (PHS 398, rev. 5/01). The instructions in the PHS 398 (rev. 5/01) describe the requirements for designing Phase III clinical trails to provide valid analysis by sex/gender and race/ethnicity. These instructions continue to be the most frequently accessed NIH documents by the research, review, and NIH staff communities.

- In January 2002, 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.

- In May 2002, an additional training session, "Inclusion of Children, Women, and Minorities: What SRA's and Reviewers Need to Know!" was held for the Center for Scientific Review on the updated policies and procedures on sex/gender and minority inclusion. This session 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.

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 trials 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. The *NIH Subcommittee Reviewing Inclusion Issues* also collected comments on the tracking system used prior to 2000 and identified issues relating to data entry, including quality control and the mechanisms of data entry. 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). The re-engineered population tracking system continues to be refined based on input from the NIH user community.

- In May 2002, NIH published an on-line users guide and began offering 2-hour Population Tracking System demonstrations to accompany the launch of the new system. To date, ten 2-hour sessions have been conducted with one session archived for subsequent staff training.

- Since July 2002, eight 3-hour, in-depth, hands-on training sessions have been provided to NIH staff on the use of the new population tracking system. Training materials for the hands-on course are available electronically to NIH staff as resource material.

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:

- In 2002, NIH staff presented "Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know!", an hour workshop on the revised inclusion policy and OMB requirements at two NIH Regional Seminar meetings. Each meeting involved 400 extramural scientists and administrators. An additional presentation was made to faculty and students at the NIH Warren G. Magnusen Clinical Center.

- 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.

- The *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research* is currently being revised and will be published in the fall of 2002. The revised Outreach Notebook will include additional information for principal investigators on updated NIH inclusion policy, 1997 OMB requirements for reporting race and ethnicity data, information for submitting an application, application submission, peer review, and funding. The publication will be posted on the NIH website for the inclusion of women and minorities policy implementation at: http://grants.nih.gov/grants/funding/women_min/women_min.htm as well as on the ORWH website http://www4.od.nih.gov/orwh/fy97-98trkg.pdf.

- In addition, the Questions and Answers section of the *Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research* is currently being revised and will be published as Frequently Asked Questions (FAQs) on the NIH website for the inclusion of women and minorities policy implementation at: http://grants.nih.gov/grants/funding/women_min/women_min.htm as well as on the ORWH website http://www4.od.nih.gov/orwh/fy97-98trkg.pdf. These FAQs are being developed to provide additional guidance to researchers and NIH staff and accompany the Outreach Notebook.

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.

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.

NIH Aggregate Extramural and Intramural Population Data

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.

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. Aggregate data are reported annually by Fiscal Year (FY). The data tables included in this comprehensive report are the final reports from the old tracking system and that relied solely on data submitted using the previous 1977 OMB standards for collecting and reporting data on ethnicity and race. Future reports will rely on the new population tracking system and will include data reported according to both the 1977 and the 1997 OMB standards. Projects that began using the old standard will continue to be reported according to the 1977 standard, but all new projects will be reported according to the 1997 standard. As a result, comparisons will no longer be possible between the data reported in previous years and data reported for this year.

Tables 1 to 10 provide aggregate enrollment data for extramural and intramural research protocols funded in FY1999 and FY2000. Previous inclusion reports and aggregate enrollment figures for FY1994 through FY1999 for women and men and minority groups may be found on the ORWH website at http://od.nih.gov/orwh/inclusion.html. Following the format of the aggregate extramural data tables, the aggregate data figures for the on-site and off-site intramural research protocols are combined and presented as one single data table rather than as separate data tables for on-site and off-site intramural research protocols.

Analysis of the FY2000 inclusion data show that substantial numbers of both women 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. During FY2000, more than 95% of applications involving human subjects met the inclusion requirements as submitted to the Initial Review Group [see Table A]. Of those selected for award, more than 96% were determined to have met the inclusion requirements as submitted. All of the remaining 4% of applications selected for award were required to address and resolve satisfactorily any issues pertaining to the inclusion requirements prior to funding [see Table B].

Aggregate enrollment data for extramural Phase III trials funded in FY2000 show that approximately 70.9% of the subjects were women an increase of 7.6% from FY1999. Among minority subjects,[1] representation in Phase III trials [Table 5] was highest for Black (not Hispanic) subjects (12.1%) and lowest for American Indians/Alaskan Natives subjects (0.7%) a decrease of 0.5% and 0.1% respectively. Asian/Pacific Islanders subjects were 1.9% of the extramural Phase III subjects for FY2000 a decrease of 2.9% from FY1999; Hispanic subjects were 5.6% a decrease of 0.5%; and White (not Hispanic) subjects were 72.7% an increase of 5% from FY1999. Over nine million subjects were included in the research projects covered by the tracking system in FY2000. This snapshot of aggregate enrollment data for FY2000 extramural studies [Table 1] shows that approximately 61.3% of the subjects were women, approximately 38.4% were men, and approximately 0.4% were not identified by sex/gender. Overall, the number of women participants decreased by 0.3%, the number of men increased by 0.7% and the number of subjects that did not identify their sex/gender decreased by 0.2% compared to FY1999.

The Tracking and Inclusion Committee conducted an analysis of the FY2000 and FY1999 extramural and Phase III research protocols and noted differences in the numbers and percentages of subjects that identified their race/ethnicity in those that did not identify their sex/gender. In response to these findings, committee representatives reviewed their institute's data and reconvened the committee to discuss

---

[1] Racial and ethnic categories are in accord with the Office of Management and Budget (OMB) Directive No. 15.

possible explanations. In many cases, the changes in percentages between FY 1999 and FY 2000 were attributable to the ending of previously reported studies where enrollments involved between 20,000 – 300,000 participants per study. Although other new studies were launched in FY2000, enrollment for these new studies is just beginning. Other reasons for the fluctuations between FY1999 and FY2000 enrollment percentages included: improved reporting and corrections of errors by investigators, and; recognition that information on sex/gender and ethnicity/race is obtained voluntarily from study participants and, as a result, some participants will elect not to report this information, i.e., the information is “Unknown.” Data entry error was also an issue addressed by NIH staff; the aggregate report data tables reflect reconciled data.

Substantial numbers of women and minorities were also included in NIH intramural studies in FY2000 [Table 9]. Approximately 45.8% of intramural subjects were women and approximately 53.8% were men. Among minority subjects, representation in intramural studies was highest for Asian/Pacific Islander subjects (20.6%) and lowest for American Indian/Alaskan native subjects (0.9%). Black – (not Hispanic) subjects represented approximately 5.7% of the subjects; Hispanic subjects 2.6%; and White (not Hispanic) subjects represented 66.5% of the intramural research study population. Approximately two million subjects were included in the tracking system from intramural research projects in FY2000.

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.

REFERENCES

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

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

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

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

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

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

7. Hayunga, E. G. and Pinn V. W., "NIH Response to Researchers' Concerns", *Applied Clinical Trials*, Vol. 5, No. 11, p. 59-64, 1996.

8. LaRosa, J. H., Seto, B., Caban, C. E., Hayunga, E. G., "Including Women and Minorities in Clinical Research", *Applied Clinical Trials*, Vol. 4, No. 5, p. 31-38, 1995.

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

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

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

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

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

Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review

Council Dates		**Jan-95**	**May-95**	**Aug-95**	**Oct-95**	**Jan-96**	**May-96**	**Aug-96**	**Oct-96**	**Jan-97**	**May-97**	**Aug-97**	**Oct-97**
Total Number of Applications Reviewed	(#)	12,886	14,027	424	12,832	12,028	12,125	846	11,760	12,037	12,082	505	12,402
Number of Applications with Human Subjects	(#)	5,101	5,359	162	5,260	4,521	4,676	374	4,653	4,562	4,704	271	4,671
Number (percent) of applications approved by IRG as submitted	(#)	4,707	4,986	157	4,914	4,218	4,385	360	4,359	4,250	4,379	259	4,382
	(%)	92.28%	93.04%	96.91%	93.42%	93.30%	93.78%	96.26%	93.68%	93.16%	93.09%	95.57%	93.81%
Number (percent) of applications with unacceptable minority inclusion	(#)	175	131	1	126	146	115	4	129	134	115	2	104
	(%)	3.43%	2.44%	0.62%	2.40%	3.23%	2.46%	1.07%	2.77%	2.94%	2.44%	0.74%	2.23%
Number (percent) of applications with unacceptable sex/gender inclusion	(#)	33	29	2	22	21	23	1	14	17	20	6	20
	(%)	0.65%	0.54%	1.23%	0.42%	0.46%	0.49%	0.27%	0.30%	0.37%	0.43%	2.21%	0.43%
Number (percent) of applications with both unacceptable minority AND sex/gender inclusion	(#)	186	213	2	198	136	153	9	151	161	190	4	165
	(%)												
Total Number (percent) of applications with unacceptable minority inclusion	(#)	361	344	3	324	282	268	13	280	295	305	6	269
	(%)	7.08%	6.42%	1.85%	6.16%	6.24%	5.73%	3.48%	6.02%	6.47%	6.48%	2.21%	5.76%
Total Number (percent) of applications with unacceptable sex/gender inclusion	(#)	219	242	4	220	157	176	10	165	178	210	10	185
	(%)	4.29%	4.52%	2.47%	4.18%	3.47%	3.76%	2.67%	3.55%	3.90%	4.46%	3.69%	3.96%
Total number (percent) unacceptable applications as submitted	(#)	394	373	5	346	303	291	14	294	312	325	12	289
	(%)	7.72%	6.96%	3.09%	6.58%	6.70%	6.22%	3.74%	6.32%	6.84%	6.91%	4.43%	6.19%

Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review (continued)

Council Dates		**Jan-98**	**May-98**	**Aug-98**	**Oct-98**	**Jan-99**	**May-99**	**Aug-99**	**Oct-99**	**Jan-00**	**May-00**	**Aug-00**	**Oct-00**
Total Number of Applications Reviewed	**(#)**	11,149	12,918	589	12,484	12,603	14,340	700	13,965	13,195	14,967	906	13,716
Number of Applications with Human Subjects	**(#)**	4,252	5,005	295	4,849	4,940	5,603	451	5,560	5,255	6,160	406	5,772
Number (percent) of applications approved by IRG as submitted	**(#)**	3,977	4,705	276	4,530	4,635	5,246	413	5,242	4,967	5,825	390	5,465
	(%)	93.53%	94.01%	93.56%	93.42%	93.83%	93.63%	91.57%	94.28%	94.51%	94.56%	96.05%	94.68%
Number (percent) of applications with unacceptable minority inclusion	**(#)**	114	118	7	120	133	115	20	133	115	119	8	112
	(%)	2.68%	2.36%	2.37%	2.47%	2.69%	2.05%	4.43%	2.39%	2.18%	1.93%	1.97%	1.94%
Number (percent) of applications with unacceptable sex/gender inclusion	**(#)**	27	24	3	26	20	28	5	23	30	25	0	28
	(%)	0.63%	0.48%	1.02%	0.54%	0.40%	0.50%	1.11%	0.41%	0.57%	0.40%	0.00%	0.48%
Number (percent) of applications with both unacceptable minority AND sex/gender inclusion	**(#)**	134	158	9	173	152	214	13	162	143	191	16	167
	(%)												
Total Number (percent) of applications with unacceptable minority inclusion	**(#)**	248	276	16	293	285	329	33	295	258	310	16	279
	(%)	5.83%	5.51%	5.42%	6.04%	5.77%	5.87%	7.32%	5.31%	4.90%	5.03%	3.94%	4.83%

Table B. Extramural Research Awards: Bars to Funding and Resolutions

Council Dates		**Jan-95**	**May-95**	**Aug-95**	**Oct-95**	**Jan-96**	**May-96**	**Aug-96**	**Oct-96**	**Jan-97**	**May-97**	**Aug-97**	**Oct-97**
Total number of awards	(#)	3,476	3,902	129	3,344	3,548	3,759	228	3,378	3,874	3,958	222	3,817
Number of awards involving human subjects	(#)	1,287	1,421	51	1,263	1,260	1,352	92	1,254	1,394	1,470	106	1,401
Number (percent) of awards involving human subjects that met the inclusion requirements as submitted	(#)	1,224	1,330	50	1,189	1,178	1,277	89	1,198	1,305	1,374	101	1,324
	(%)	95.10%	93.60%	98.04%	94.14%	93.49%	94.45%	96.74%	95.53%	93.62%	93.47%	95.28%	94.50%
Number (percent) of awards where *minority only* bar-to-funding was removed by program staff (M_U)	(#)	29	26		22	43	29	0	22	38	47	0	24
	(%)	2.25%	1.83%	0.00%	1.74%	3.41%	2.14%	0.00%	1.75%	2.73%	3.20%	0.00%	1.71%
Number (percent) of awards where *sex/gender only* bar-to-funding was removed by program staff (G_U)	(#)	3	6		3	3	3	0	3	8	5	4	10
	(%)	0.23%	0.42%	0.00%	0.24%	0.24%	0.22%	0.00%	0.24%	0.57%	0.34%	3.77%	0.71%
Number (percent) of awards where both minority AND sex/gender bar-to-funding was removed by program staff	(#)	31	59	1	49	36	43	3	31	43	44	1	43
	(%)	2.41%	4.15%	1.96%	3.88%	2.86%	3.18%	3.26%	2.47%	3.08%	2.99%	0.94%	3.07%
Total number (percent) of awards where minority bar-to-funding was removed by program staff	(#)	60	85	1	71	79	72	3	53	81	91	1	67
	(%)	4.66%	5.98%	1.96%	5.62%	6.27%	5.33%	3.26%	4.23%	5.81%	6.19%	0.94%	4.78%
Total number (percent) of awards where sex/gender bar-to-funding was removed by program staff	(#)	34	65	1	52	39	46	3	34	51	49	5	53
	(%)	2.64%	4.57%	1.96%	4.12%	3.10%	3.40%	3.26%	2.71%	3.66%	3.33%	4.72%	3.78%
Total number (percent) of awards where bar-to-funding was removed	(#)	63	91	1	74	82	75	3	56	89	96	5	77
	(%)	4.90%	6.40%	1.96%	5.86%	6.51%	5.55%	3.26%	4.47%	6.38%	6.53%	4.72%	5.50%

Table B. Extramural Research Awards: Bars-To Funding and Resolutions (continued)

Council Dates		**Jan-98**	**May-98**	**Aug-98**	**Oct-98**	**Jan-99**	**May-99**	**Aug-99**	**Oct-99**	**Jan-00**	**May-00**	**Aug-00**	**Oct-00**
Total number of awards	(#)	3,863	4,363	209	4,019	4,247	4,824	298	4,278	4,415	4,960	307	4,389
Number of awards involving human subjects	(#)	1,431	1,594	104	1,442	1,625	1,832	156	1,616	1,633	1,964	129	1,683
Number (percent) of awards involving human subjects that met the inclusion requirements as submitted	(#)	1,368	1,524	98	1,370	1,556	1,753	143	1,552	1,582	1,893	124	1,632
	(%)	95.60%	95.61%	94.23%	95.01%	95.75%	95.69%	91.67%	96.04%	96.87%	96.38%	96.12%	96.96%
Number (percent) of awards where *minority only* bar-to-funding was removed by program staff (M_U)	(#)	30	17	3	30	21	31	5	25	18	27	1	23
	(%)	2.10%	1.07%	2.88%	2.08%	1.29%	1.69%	3.21%	1.55%	1.10%	1.37%	0.77%	1.36%
Number (percent) of awards where *sex/gender only* bar-to-funding was removed by program staff (G_U)	(#)	9	7	1	8	9	9	2	4	13	7	0	8
	(%)	0.63%	0.44%	0.96%	0.55%	0.55%	0.49%	1.28%	0.25%	0.79%	0.35%	0.00%	0.47%
Number (percent) of awards where both minority AND sex/gender bar-to-funding was removed by program staff	(#)	24	46	2	34	39	39	6	35	20	37	4	20
	(%)	1.68%	2.89%	1.92%	2.36%	2.40%	2.13%	3.85%	2.17%	1.22%	1.88%	3.10%	1.18%
Total number (percent) of awards where minority bar-to-funding was removed by program staff	(#)	54	63	5	64	60	70	11	60	38	64	5	43
	(%)	3.77%	3.95%	4.81%	4.44%	3.69%	3.82%	7.05%	3.71%	2.32%	3.25%	3.87%	2.55%
Total number (percent) of awards where sex/gender bar-to-funding was removed by program staff	(#)	33	53	3	42	48	48	8	39	33	44	4	28
	(%)	2.31%	3.32%	2.88%	2.91%	2.95%	2.62%	5.13%	2.41%	2.02%	2.24%	3.10%	1.66%
Total number (percent) of awards where bar-to-funding was removed	(#)	63	70	6	72	69	79	13	64	51	71	5	51
	(%)	4.40%	4.39%	5.77%	4.99%	4.25%	4.31%	8.33%	3.96%	3.12%	3.61%	3.87%	3.03%

Table C. Inclusion by Sex in All Research Studies Receiving Funding in FY1999

	Extramural Studies		Intramural Studies	
	Phase III trials*	Other clinical research**	On-site	Off-site
Protocols reporting women only	114	773	90	36
Protocols reporting men only	34	294	64	14
Protocols reporting both women and men	369	4,323	848	155
Protocols involving men, women and Unknown***	24	259		26
Protocols where sex composition was reported as Unknown	2	57		10
Protocols reporting men and Unknown	2	6		1
Protocols reporting women and Unknown	0	8		1
Early Stage studies where enrollment data has not yet been collected	44	1,632	128	69
Totals	**589**	**7,352**	**1,130**	**312**

* 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.

*** Many studies may be generic.

Table C Inclusion by Sex in All Research Studies Receiving Funding in FY2000

	Extramural Studies		Intramural Studies	
	Phase III trials*	Other clinical research**	On-site	Off-site
Protocols reporting women only	121	854	90	33
Protocols reporting men only	34	326	67	12
Protocols reporting both women and men	411	5,131	845	150
Protocols involving men, women and Unknown***	31	280		29
Protocols where sex composition was reported as Unknown	0	35		7
Protocols reporting men and Unknown	2	5		
Protocols reporting women and Unknown	0	7		
Early Stage studies where enrollment data has not yet been submitted	46	1,504	129	65
Totals	**645**	**8,142**	**1,131**	**296**

* 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.

*** Many studies may be generic.

Table C-1. Examples of Single Sex Extramural Research Studies

Examples of Studies of Selected Protocols that include Male-Only Human Subjects

Nutritional and Hormonal Biomarkers in Prostate Cancer
Testosterone and Bone Mineral Density in Elderly Men
Bone Loss in Vertebral Fractures in Older Men
Head Injury & Alzheimer's Disease
Genetic Epidemiology of Alzheimer's Disease in Twins
Epidemiology of Male Infertility - Cryptorchidism
Medical Therapy for BPH - Data Coordinating Center
HIV Prevention Intervention for Young Men
Dietary Etiologies of Heart Disease and Cancer
Managing Uncertainty in Stage B Prostate Cancer
Comprehensive HBP Care for Young Urban Black Men
Follow-up Study of Neurological Risks in Amateur Boxers
Serum Albumin, Orthostatic Hypotension in Frail
GU Sites in Men
Psychophysiology of Visible and Invisible Trauma

Examples of Studies of Selected Protocols that include Female-Only Human Subjects

Breast Cancer Surveillance in a Defined Population
Osteoporotic Fractures
Women's Health and Aging Study
Cesarean Section Reduction in Primigravid Patients
Diet, Activity and Adolescent Weight Changes
Alternative Interventions for Battered Women
Trial of Vitamin E, Beta-Carotene and Aspirin in Women
Genetic Epidemiology of Blood Lipids and Obesity
Endogenous Estrogen & Coronary Heart Disease in Women
Women's Health Initiative
Risk Factors for Cardiovascular Disease in Women
Cross Ethnic Nursing Study of Weight Management in Women
Women's Estrogen for Stroke Trial (West)
Detection of Presymptomatic Alzheimer's Disease by FMRI
Women's Estrogen for Stroke Trial
Diagnosis of Perinatal HIV Infection in Puerto Rico
Persistence or Transience of HPV Infection in Women
Urine Screening Test to Detect Bacteruiuria in Pregnancy
Women's Interagency HIV Study
Connective Tissue Role in Urinary Stress Incontinence
Infant Mortality in Rural Yunnan, China

Aggregate Enrollment Data Tables for Extramural and Intramural Research Protocols

(Fiscal Years 1999 and 2000)

Table 1 (2000) Aggregate Enrollment Data for All Extramural Research Protocols Funded in FY2000

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	45,828	0.8%	728,385	12.3%	650,459	10.9%	422,476	7.1%	3,797,984	63.9%	295,742	5.0%	5,940,874	61.3%
Male	42,000	1.1%	372,842	10.0%	436,833	11.7%	345,394	9.3%	2,243,973	60.3%	280,166	7.5%	3,721,208	38.4%
Unknown	205	0.6%	2,779	7.9%	4,128	11.7%	1,827	5.2%	10,053	28.6%	16,167	46.0%	35,159	0.4%
Total	88,033	0.9%	1,104,006	11.4%	1,091,420	11.3%	769,697	7.9%	6,052,010	62.4%	592,075	6.1%	9,697,241	100.0%

Number of Protocols: 8,785

Table 2 (1999) Aggregate Enrollment Data for All Extramural Research Protocols Funded in FY1999

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	33,991	0.7%	829,502	18.2%	653,412	14.4%	313,065	6.9%	2,468,041	54.2%	254,403	5.6%	4,552,414	61.6%
Male	29,707	1.1%	247,475	8.9%	451,895	16.2%	221,781	8.0%	1,633,898	58.6%	202,372	7.3%	2,787,128	37.7%
Unknown	288	0.6%	855	1.9%	4,179	9.3%	16,084	35.6%	5,820	12.9%	17,913	39.7%	45,139	0.6%
Total	63,986	0.9%	1,077,832	14.6%	1,109,486	15.0%	550,930	7.5%	4,107,759	55.6%	474,688	6.4%	7,384,681	100.0%

Number of Protocols: 7,948

Aggregate Enrollment Data for All Extramural Research Protocols

FY00 Data Table Comments:

More females (5,940,874 or 61.3%) than males (3,721,208 or 38.4%) are enrolled in aggregate Extramural Research protocols.
Largest identified racial group is White, non-Hispanic at 62.4%.
Largest identified racial minority group is Asian/Pacific Islanders at 11.4%.
Smallest identified racial minority group is American Indian/Alaska Natives at 0.9%.

FY99 Data Table Comments:

More females (4,552,414 or 61.6%) than males (2,787,128 or 37.7) are enrolled in aggregate Extramural Research protocols.
Largest identified racial group is White, non-Hispanic at 55.6%.
Largest identified racial minority groups is Black, non-Hispanic at 15.0%.
Smallest identified racial minority group is American Indian/Alaska Natives at 0.9%.

Table 3 (2000) Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only & Female Only Protocols Funded in FY2000

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	40,261	1.1%	354,982	9.9%	459,924	12.8%	345,866	9.6%	2,183,755	60.8%	205,104	5.7%	3,589,892	50.2%
Male	40,567	1.2%	345,952	9.8%	421,657	12.0%	333,218	9.5%	2,105,264	59.8%	274,424	7.8%	3,521,082	49.3%
Unknown	205	0.6%	2,779	7.9%	4,128	11.7%	1,827	5.2%	10,053	28.6%	16,167	46.0%	35,159	0.5%
Total	81,033	1.1%	703,713	9.8%	885,709	12.4%	680,911	9.5%	4,299,072	60.2%	495,695	6.9%	7,146,133	100.0%

Number of Protocols: 5,897

Table 4 (1999) Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only & Female-Only Protocols Funded in FY1999

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	29,853	1.2%	167,725	6.8%	504,250	20.4%	258,584	10.4%	1,318,085	53.2%	197,183	8.0%	2,475,680	50.1%
Male	29,459	1.2%	159,956	6.6%	420,593	17.3%	216,121	8.9%	1,402,815	57.8%	197,582	8.1%	2,426,526	49.1%
Unknown	288	0.7%	855	1.9%	4,179	9.5%	16,084	36.5%	5,820	13.2%	16,840	38.2%	44,066	0.9%
Total	59,600	1.2%	328,536	6.6%	929,022	18.8%	490,789	9.9%	2,726,720	55.1%	411,605	8.3%	4,946,272	100.0%

Number of Protocols: 5,049

Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only & Female-Only Protocols

FY00 Data Table Comments:

There were 8,785 protocols of which 975 were women only protocols and 360 were men only protocols.
Largest identified racial group is White, non-Hispanic at 4,299,072 or 60.2%.
Largest identified racial minority group is Black - Not Hispanic at 885,709 or 12.4%.
Smallest identified racial minority group is American Indian/Alaska Native at 81,033 or 1.1%.

FY99 Data Table Comments:

There were 7,948 extramural protocols of which 888 were women-only protocols and 328 were men-only protocols.
Largest identified racial group is White, non-Hispanic at 2,726,720 or 55.1%.
Largest identified racial minority group is Black - Not Hispanic at 929,022 or 18.8%.
Smallest identified racial minority group is American Indian/Alaska Native at 59,600 or 1.2%.

Table 5 (2000) Aggregate Enrollment Data for Extramural Phase III Protocols Funded in FY2000

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	2,521	0.6%	8,920	2.2%	46,303	11.2%	20,889	5.1%	309,289	75.0%	24,457	5.9%	412,379	70.9%
Male	1,558	0.9%	2,205	1.3%	23,606	14.0%	11,606	6.9%	113,068	67.3%	16,042	9.5%	168,085	28.9%
Unknown	0	0.0%	7	0.5%	201	15.8%	57	4.5%	445	35.0%	563	44.2%	1,273	0.2%
Total	4,079	0.7%	11,132	1.9%	70,110	12.1%	32,552	5.6%	422,802	72.7%	41,062	7.1%	581,737	100.0%

Number of Protocols : 645

Table 6 (1999) Aggregate Enrollment Data for Extramural Phase III Protocols Funded in FY1999

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	2,132	0.7%	13,314	4.2%	37,827	12.0%	17,097	5.4%	221,098	70.4%	22,484	7.2%	313,952	63.3%
Male	1,590	0.9%	10,697	5.9%	24,605	13.6%	12,950	7.2%	114,416	63.3%	16,447	9.1%	180,705	36.5%
Unknown	4	0.4%	6	0.6%	80	7.4%	37	3.4%	310	28.5%	649	59.8%	1,086	0.2%
Total	3,726	0.8%	24,017	4.8%	62,512	12.6%	30,084	6.1%	335,824	67.7%	39,580	8.0%	495,743	100.0%

Number of Protocols : 589

Aggregate Enrollment Data for Extramural Phase III Protocols

FY00 Data Comments:

Substantial numbers of women and minorities are enrolled in Phase III research protocols funded in 2000.
There were more females (412,379 or70.9%) than males (168,085 or 28.9%) enrolled in Phase III research protocols.
Among minority subjects, the largest racial minority group is Black, non-Hispanic at 70,110 or 12%.
Smallest identified racial group is American Indian/Alaska Natives at 4,079 or 0.7%.

FY99 Data Comments:

Substantial numbers of women and minorities are enrolled in Phase III research protocols funded in 1999.
There were more females (313,952 or 63.3%) than males (180,705 or 36.5%) enrolled in Phase III research protocols.
Among minority subjects, the largest racial minority group is Black, non-Hispanic at 62,512 or 12.6%.
Smallest identified racial group is American Indian/Alaska Natives at 3,726 or 0.8%.

Table 7 (2000) Aggregate Enrollment Data for Extramural Phase III Research Protocols Excluding Male-Only & Female Only Protocols Funded in FY2000

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	1,383	1.1%	1,750	1.3%	21,977	16.9%	10,567	8.1%	74,761	57.5%	19,541	15.0%	129,979	45.4%
Male	1,526	1.0%	2,096	1.4%	21,469	13.8%	11,125	7.2%	103,862	66.9%	15,145	9.8%	155,223	54.2%
Unknown	0	0.0%	7	0.5%	201	15.8%	57	4.5%	445	35.0%	563	44.2%	1,273	0.4%
Total	2,909	1.0%	3,853	1.3%	43,647	15.2%	21,749	7.6%	179,068	62.5%	35,249	12.3%	286,475	100.0%

Number of Protocols: 444

Table 8 (1999) Aggregate Enrollment Data for Extramural Phase III Research Protocols Excluding Male-Only & Female Only Protocols Funded in FY1999

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	1,422	1.1%	9,070	6.9%	22,144	16.9%	10,939	8.3%	68,168	51.9%	19,571	14.9%	131,314	45.9%
Male	1,557	1.0%	10,109	6.6%	21,097	13.7%	11,589	7.5%	94,761	61.4%	15,099	9.8%	154,212	53.8%
Unknown	4	0.5%	6	0.7%	80	9.3%	37	4.3%	310	36.0%	423	49.2%	860	0.3%
Total	2,983	1.0%	19,185	6.7%	43,321	15.1%	22,565	7.9%	163,239	57.0%	35,093	12.3%	286,386	100.0%

Number of Protocols: 396

Aggregate Enrollment Data for Extramural Phase III Research Protocols Excluding Male-Only & Female-Only Protocols

FY00 Data Table Comments

There were 645 protocols of which 121 were women only protocols and 34 were men only protocols.
Largest identified racial group is White, non-Hispanic at 179,068 or 62.5%.
Largest identified racial minority group is Black - Not Hispanic at 43,647 or 15.2%.
Smallest identified racial minority group is American Indian/Alaska Native at 2,909 or 1.0%.

FY99 Data Table Comments

There were 589 protocols of which 114 were women-only protocols and 34 were men-only protocols.
Largest identified racial group is White, non-Hispanic at 163,239 or 57.0%.
Largest identified racial minority group is Black - Not Hispanic at 43,321 or 15.1%.
Smallest identified racial minority group is American Indian/Alaska Native at 2,983 or 1.0%.

Table 9 (2000). Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2000 (Includes On-site and Off-site)

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	9,042	1.0%	198,427	22.9%	53,713	6.2%	29,928	3.4%	546,363	62.9%	30,475	3.5%	867,948	45.8%
Male	7,991	1.1%	192,775	18.9%	54,470	5.3%	19,392	1.9%	715,671	70.2%	29,380	2.9%	1,019,679	53.8%
Unknown	1	0.0%	71	0.8%	22	0.2%	131	1.4%	405	4.3%	8,758	93.3%	9,388	0.5%
Total	17,034	0.9%	391,273	20.6%	108,205	5.7%	49,451	2.6%	1,262,439	66.5%	68,613	3.6%	1,897,015	100.0%

Number of Protocols: 1,427

Table 10 (1999). Aggregate Enrollment Data for Intramural Research Protocols Funded in FY1999 (Includes On-site and Off-site)

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	9,910	1.0%	242,790	23.5%	55,288	5.4%	20,863	2.0%	654,775	63.4%	49,002	4.7%	1,032,628	47.3%
Male	8,810	0.8%	204,676	18.1%	44,756	4.0%	16,588	1.5%	823,213	72.7%	33,894	3.0%	1,131,937	51.8%
Unknown	22	0.1%	94	0.5%	239	1.2%	27	0.1%	3,195	16.1%	16,274	82.0%	19,851	0.9%
Total	18,742	0.9%	447,560	20.5%	100,283	4.6%	37,478	1.7%	1,481,183	67.8%	99,170	4.5%	2,184,416	100.0%

Number of Protocols: 1,439

Aggregate Enrollment Data for Intramural Research Protocols

FY00 Data Comments

There were more males (1,019,679 or 53.8%) than females (867,948 or 45.8%) enrolled in aggregate Intramural research protocols.

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

The racial minority group with the largest increase in enrollment is Hispanic - an increase of 75% from FY99 to FY00.

The number of Black - Not Hispanic enrollees increased by 8% from FY99 to FY00.

Largest identified racial minority group is Asian/Pacific Islanders at 391,273 or 20.6%.

The large Asian/Pacific Islander population is due in part to a large clinical study being conducted in Vietnam.

Smallest identified racial minority group is American Indian/Alaskan Native at 17,034 or 0.9%.

FY99 Data Comments

There were more males (1,131,937 or 51.8%) than females (1,032,628 or 47.3%) enrolled in aggregate Intamural research protocols.

Differences in the enrollment of males and females is attributed primarily to improvements in reporting procedures. (ie, ensuring gender declaration and recording at enrollment).

The racial minority group with the largest increase in enrollment is Hispanic - an increase of 75% from FY98 to FY99.

The number of Black - Not Hispanic enrollees increased by 30% from FY98 to FY99.

Largest identified racial minority group is Asian/Pacific Islanders at 446, 918 or 20.5%.

The large Asian/Pacific Islander population is due in part to a large clinical study being conducted in Vietnam.

Smallest identified racial minority group is American Indian/Alaskan Native at 18,692 or 0.9%.

Patient enrollment in the intramural research program at the Warren Grant Magnuson Clinical Center increased by 45% in FY99 compared to FY98.

Table 11 (2000). Aggregate Enrollment Data for Intramural Research Protocols Excluding Male-Only & Female Only Protocols Funded in FY2000 (Includes On-site & Offsite)

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	8,540	1.1%	194,866	25.9%	45,648	6.1%	11,445	1.5%	464,184	61.8%	26,976	3.6%	751,659	42.9%
Male	7,976	1.1%	192,715	19.4%	53,889	5.4%	19,297	1.9%	689,035	69.4%	29,315	3.0%	992,227	56.6%
Unknown	1	0.0%	71	0.8%	22	0.2%	131	1.4%	405	4.3%	8,758	93.3%	9,388	0.5%
Total	16,517	0.9%	387,652	22.1%	99,559	5.7%	30,873	1.8%	1,153,624	65.8%	65,049	3.7%	1,753,274	100.0%

Number of Protocols: 1,031

Table 12 (2000). Aggregate Enrollment Data for Intramural Phase III Research Protocols Funded in FY2000 (Includes On-site and Off-site)

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	101	1.4%	5,877	82.5%	81	1.1%	22	0.3%	809	11.4%	230	3.2%	7,120	47.0%
Male	40	1.1%	6,196	77.3%	115	1.4%	39	0.5%	1,406	17.5%	221	2.8%	8,017	53.0%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0%
Total	141	0.9%	12,073	79.8%	196	1.3%	61	0.4%	2,215	14.6%	451	3.0%	15,137	100.0%

Number of Protocols: 32

Summary Report of Total Enrollment Data for All Extramural and Phase III Research Protocols Sorted by Institutes and Centers

(Fiscal Years 1999 and 2000)

FY00 and FY99 Enrollment Data Analysis by Institute and Center (All Extramural)

NIAAA Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	32,726	1.4%	350,343	15.1%	158,604	7.0%	264,364	11.7%	1,430,064	63.1%	29,858	1.3%	2,265,959	100.0%
FY99	4,144	0.8%	14,115	2.6%	132,872	24.7%	34,172	6.4%	340,245	63.3%	11,704	2.2%	537,252	100.0%

NIA Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	913	0.2%	19,255	4.2%	39,251	8.6%	11,215	2.5%	323,207	71.1%	60,695	13.4%	454,536	100.0%
FY99	695	0.2%	17,614	4.7%	25,583	6.9%	7,457	2.0%	264,209	70.8%	57,499	15.4%	373,057	100.0%

NIAID Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	1,725	0.7%	16,062	6.2%	72,497	27.9%	29,252	11.2%	126,529	48.7%	14,003	5.4%	260,068	100.0%
FY99	1,111	0.4%	13,067	5.0%	77,475	29.6%	30,511	11.7%	99,528	38.0%	39,911	15.3%	261,603	100.0%

NIAMS Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	824	0.9%	2,427	2.6%	6,680	7.0%	3,861	4.1%	47,886	50.4%	33,391	35.1%	95,069	100.0%
FY99	656	0.7%	1,909	2.1%	8,997	10.1%	3,187	3.6%	41,185	46.2%	33,169	37.2%	89,103	100.0%

NCCAM Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	7	0.1%	64	1.3%	439	8.7%	163	3.2%	4,267	84.5%	108	2.1%	5,048	100.0%
FY99	3	0.1%	19	0.6%	520	16.0%	43	1.3%	2,647	81.7%	9	0.3%	3,241	100.0%

NCI Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	6,712	0.2%	566,248	19.5%	184,677	6.4%	153,633	5.3%	1,720,735	59.3%	270,188	9.3%	2,902,193	100.0%
FY99	5,793	0.2%	890,185	31.1%	191,017	6.7%	100,125	3.5%	1,560,313	54.5%	113,874	4.0%	2,861,307	100.0%

NCI - CN Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	484	0.3%	6,573	4.2%	9,301	6.0%	3,103	2.0%	136,600	87.4%	218	0.1%	156,279	100.0%
FY99														

NIDA Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	9,478	1.7%	19,295	3.6%	119,886	22.1%	83,327	15.3%	272,553	50.2%	38,711	7.1%	543,250	100.0%
FY99	18,343	1.8%	10,331	1.0%	259,909	26.0%	153,517	15.3%	474,734	47.4%	84,713	8.5%	1,001,547	100.0%

NIDCD Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	156	0.2%	2,155	2.3%	2,511	2.7%	1,602	1.7%	82,224	89.2%	3,546	3.8%	92,194	100.0%
FY99	175	0.2%	2,414	2.5%	2,031	2.1%	1,744	1.8%	85,465	89.8%	3,306	3.5%	95,135	100.0%

NIDCR Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	262	0.7%	2,443	6.8%	4,670	13.1%	2,215	6.2%	21,946	61.5%	4,165	11.7%	35,701	100.0%
FY99	98	0.3%	425	1.4%	5,375	17.7%	847	2.8%	21,838	71.8%	1,814	6.0%	30,397	100.0%

NIDDK Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	3,936	3.0%	8,161	6.2%	18,448	14.0%	19,312	14.6%	80,908	61.2%	1,341	1.0%	132,106	100.0%
FY99	3,530	7.8%	1,826	4.0%	5,244	11.6%	6,603	14.6%	27,384	60.6%	585	1.3%	45,172	100.0%

NIEHS Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	681	2.2%	3,867	12.4%	4,355	13.9%	5,745	18.4%	15,489	49.6%	1,110	3.6%	31,247	100.0%
FY99	1,039	2.6%	3,488	8.8%	4,774	12.0%	6,010	15.1%	23,005	57.7%	1,543	3.9%	39,859	100.0%

NEI Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	1,408	3.7%	1,232	3.2%	5,343	13.9%	3,403	8.8%	26,186	68.0%	929	2.4%	38,501	100.0%
FY99	1,663	2.6%	2,266	3.5%	6,123	9.6%	4,156	6.5%	45,113	70.4%	4,724	7.4%	64,045	100.0%

NIGMS Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	13	0.7%	18	0.9%	232	11.8%	219	11.1%	1,343	68.3%	142	7.2%	1,967	100.0%
FY99	3	0.2%	20	1.5%	94	7.0%	98	7.2%	1,021	75.5%	116	8.6%	1,352	100.0%

NICHD Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	4,131	1.4%	17,485	5.8%	70,366	23.4%	36,787	12.2%	157,691	52.3%	14,768	4.9%	301,228	100.0%
FY99	4,956	1.3%	72,216	18.8%	73,802	19.2%	34,812	9.1%	154,936	40.3%	43,400	11.3%	384,122	100.0%

NHGRI Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	57	1.5%	185	4.9%	807	21.4%	229	6.1%	2,295	60.8%	202	5.4%	3,775	100.0%
FY99	51	3.0%	24	1.4%	125	7.4%	147	8.6%	1,253	73.7%	100	5.9%	1,700	100.0%

NIMH Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	13,982	1.1%	45,932	3.8%	188,280	15.4%	75,760	6.2%	798,560	65.5%	97,045	8.0%	1,219,559	100.0%
FY99	10,422	1.5%	21,352	3.1%	138,570	19.9%	50,410	7.2%	418,076	59.9%	58,633	8.4%	697,463	100.0%

NINR Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	1,553	1.4%	1,811	1.6%	13,753	12.0%	4,110	3.6%	90,082	78.6%	3,369	2.9%	114,678	100.0%
FY99	301	0.9%	794	2.4%	6,516	19.6%	2,789	8.4%	17,815	53.7%	4,985	15.0%	33,200	100.0%

NINDS Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	479	0.5%	1,371	1.3%	13,494	12.7%	5,502	5.2%	82,298	77.4%	3,235	3.0%	106,379	100.0%
FY99	171	0.2%	888	1.2%	10,550	13.9%	19,346	25.5%	42,123	55.6%	2,744	3.6%	75,822	100.0%

NCRR Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	79	0.5%	3,653	25.1%	1,221	8.4%	6,368	43.8%	1,728	11.9%	1,491	10.3%	14,540	100.0%
FY99	68	0.2%	1,134	4.1%	2,275	8.2%	23,050	83.3%	708	2.6%	439	1.6%	27,674	100.0%

FIC Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	841	2.8%	4,320	14.3%	5,318	17.6%	4,562	15.1%	11,138	36.8%	4,095	13.5%	30,274	100.0%
FY99	302	2.7%	1,524	13.6%	3,425	30.6%	3,935	35.1%	1,595	14.2%	428	3.8%	11,209	100.0%

HL Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	6,589	1.1%	25,992	4.2%	128,561	20.7%	37,792	6.1%	416,496	66.9%	6,784	1.1%	622,214	100.0%
FY99	9,498	2.0%	16,903	3.6%	112,159	23.8%	36,438	7.7%	287,919	61.0%	8,966	1.9%	471,883	100.0%

HL - HB Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	36	1.5%	97	4.0%	1,095	44.6%	302	12.3%	906	36.9%	18	0.7%	2,454	100.0%
FY99	38	1.1%	188	5.6%	1,272	38.1%	485	14.5%	1,201	35.9%	158	4.7%	3,342	100.0%

HL - HC Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	182	0.2%	705	0.8%	22,792	24.5%	8,940	9.6%	60,227	64.7%	215	0.2%	93,061	100.0%
FY99	179	0.2%	677	0.8%	22,516	25.2%	8,841	9.9%	56,897	63.7%	232	0.3%	89,342	100.0%

HL - HR Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	39	0.4%	98	0.9%	3,872	36.4%	1,309	12.3%	5,103	48.0%	211	2.0%	10,632	100.0%
FY99	34	0.4%	83	0.9%	3,383	38.3%	1,010	11.4%	4,163	47.2%	151	1.7%	8,824	100.0%

HL - HV Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	22	0.9%	21	0.9%	335	13.6%	75	3.0%	2,015	81.6%	0	0.0%	2,468	100.0%
FY99	17	1.1%	2	0.1%	282	18.8%	22	1.5%	1,174	78.4%	0	0.0%	1,497	100.0%

HL - WH Aggregate Enrollment Data for All Extramural Research Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	718	0.4%	4,193	2.6%	14,632	9.0%	6,547	4.0%	133,534	82.5%	2,237	1.4%	161,861	100.0%
FY99	718	0.4%	4,193	2.6%	14,632	9.0%	6,547	4.0%	133,534	82.5%	2,237	1.4%	161,861	100.0%

FY00 and FY99 Enrollment Data Analysis by Institute and Center (Phase III Protocols)

NIAAA Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	3	4.8%	0	0.0%	7	1.3%	12	19.4%	40	64.5%	0	0.0%	62	100.0%
FY99	2	8.7%	0	0.0%	2	8.7%	5	21.7%	14	60.9%	0	0.0%	23	100.0%

NIA Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	24	0.2%	85	0.7%	462	3.8%	119	1.0%	11,358	93.4%	113	0.9%	12,161	100.0%
FY99	25	0.2%	81	0.6%	418	3.3%	219	1.7%	11,932	93.3%	110	0.9%	12,785	100.0%

NIAID Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	162	0.8%	470	2.5%	4,958	26.0%	2,788	14.6%	10,284	53.9%	401	2.1%	19,063	100.0%
FY99	149	0.8%	480	2.6%	5,685	31.3%	2,983	16.4%	8,354	46.0%	511	2.8%	18,162	100.0%

NIAMS Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	4	0.0%	29	0.1%	101	0.3%	46	0.1%	961	3.1%	30,205	96.4%	31,346	100.0%
FY99	2	0.0%	27	0.1%	79	0.3%	35	0.1%	883	2.8%	30,323	96.7%	31,349	100.0%

NCCAM Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	2	0.1%	13	0.4%	189	5.6%	26	0.8%	3,093	90.9%	79	2.3%	3,402	100.0%
FY99	0	0.0%	6	4.7%	31	24.4%	27	21.3%	59	46.5%	4	3.1%	127	100.0%

NCI Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	758	0.4%	4,053	2.3%	16,153	9.0%	9,570	5.3%	143,393	79.7%	6,042	3.4%	179,969	100.0%
FY99	685	0.4%	4,100	2.4%	13,890	8.2%	7,570	4.5%	137,277	81.2%	5,311	3.1%	168,833	100.0%

NIDA Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	117	2.1%	18	0.3%	2,319	41.7%	1,125	20.2%	1,894	34.1%	88	1.6%	5,561	100.0%
FY99	148	1.8%	112	1.3%	3,357	40.1%	952	11.4%	3,677	44.0%	119	1.4%	8,365	100.0%

NIDCD Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	0	0.0%	13	1.4%	74	7.9%	23	2.5%	819	87.8%	4	0.4%	933	100.0%
FY99	0	0.0%	3	2.9%	3	2.9%	5	4.8%	78	75.0%	15	14.4%	104	100.0%

NIDCR Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	2	0.2%	15	1.4%	254	23.7%	38	3.6%	698	65.2%	63	5.9%	1,070	100.0%
FY99	2	0.1%	15	0.7%	245	11.3%	38	1.8%	1,797	82.8%	74	3.4%	2,171	100.0%

NIDDK Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	11	0.2%	65	1.0%	1,594	24.0%	425	6.4%	4,336	65.2%	224	3.4%	6,655	100.0%
FY99	8	0.2%	45	1.3%	296	8.4%	245	7.0%	2,917	83.1%	1	0.0%	3,512	100.0%

NIEHS Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	1	0.3%	0	0.0%	258	77.7%	51	15.4%	22	6.6%	0	0.0%	332	100.0%
FY99													0	100.0%

NEI Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	38	0.5%	79	1.0%	1,187	15.6%	205	2.7%	6,037	79.3%	70	0.9%	7,616	100.0%
FY99	41	0.6%	96	1.3%	1,087	14.8%	423	5.8%	5,581	76.1%	102	1.4%	7,330	100.0%

NICHD Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	15	0.1%	274	2.6%	5,111	48.4%	863	8.2%	3,959	37.5%	333	3.2%	10,555	100.0%
FY99	50	0.2%	12,226	56.6%	2,480	11.5%	725	3.4%	6,010	27.8%	100	0.5%	21,591	100.0%

NIMH Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	155	1.1%	230	1.7%	2,239	16.6%	559	4.1%	9,896	73.2%	434	3.2%	13,513	100.0%
FY99	222	1.0%	3,620	16.1%	6,869	30.6%	2,808	12.5%	8,202	36.5%	725	3.2%	22,446	100.0%

NINDS Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	3	0.1%	13	0.5%	1,681	66.2%	31	1.2%	807	31.8%	3	0.1%	2,538	100.0%
FY99	33	0.4%	93	102.0%	2,065	26.8%	386	5.0%	4,818	62.6%	305	4.0%	7,700	100.0%

NCRR Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	0	0.0%	55	53.9%	2	2.0%	5	4.9%	37	36.3%	3	2.9%	102	100.0%
FY99	1	1.8%	8	14.5%	2	3.6%	3	5.5%	38	69.1%	3	5.5%	55	100.0%

NHLBI Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	1,865	3.3%	754	1.3%	2,738	4.8%	926	1.6%	50,056	88.1%	470	0.8%	56,809	100.0%
FY99	1,872	3.1%	786	1.3%	3,134	5.2%	1,599	2.7%	51,853	86.8%	526	0.9%	59,770	100.0%

HL - HR Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	25	0.6%	76	2.0%	465	12.1%	210	5.5%	2,990	77.7%	82	2.1%	3,848	100.0%
FY99	23	0.8%	62	2.2%	373	13.1%	177	6.2%	2,149	75.5%	62	2.2%	2,846	100.0%

HL - HV Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	22	0.9%	21	0.9%	335	13.6%	75	3.0%	2,015	81.6%	0	0.0%	2,468	100.0%
FY99	17	1.1%	2	0.1%	282	18.8%	22	1.5%	1,174	78.4%	0	0.0%	1,497	100.0%

HL - WH Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	293	0.4%	1,520	2.2%	6,988	10.3%	2,889	4.2%	55,520	81.5%	925	1.4%	68,135	100.0%
FY99	293	0.4%	1,520	2.2%	6,988	10.3%	2,889	4.2%	55,520	81.5%	925	1.4%	68,135	100.0%

HL - HB Aggregate Enrollment Data for Extramural Phase III Protocols

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	0	0.0%	9	1.2%	292	39.9%	28	3.8%	384	52.5%	18	2.5%	731	100.0%
FY99	2	0.1%	100	6.2%	469	29.0%	211	13.0%	679	41.9%	158	9.8%	1,619	100.0%

HL - HC Aggregate Enrollment Data for Extramural Phase III Protocol

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
FY00	154	0.3%	667	1.1%	15,059	24.6%	8,880	14.5%	36,189	59.2%	193	0.3%	61,142	100.0%
FY99	151	0.3%	639	1.1%	14,783	25.7%	8,781	15.3%	32,859	57.2%	210	0.4%	57,423	100.0%

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
List of Members
Year 2001-2002

Office of the Director

Yvonne Maddox

Office of Research on Women's Health

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

Office of Extramural Research

Della Hann*, Larry Fanning, Donna Frahm

Office of Acquisition, Management and Procurement

Zaiga Tums, Barbara Levy, Joann Wingard

National Cancer Institute

Marvin Kalt*, Diane Bronzert, Marilyn Gaston, Joe Harford, Margaret Holmes, Kim Witherspoon

National Eye Institute

Lore Anne McNicol*, William Darby

National Heart, Lung, and Blood Institute

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

National Human Genome Research Institute

Karen Hajos*, Susan Saylor

National Institute on Aging

Miriam Kelty *, Karen Bashir, Taylor Harden

National Institute on Alcohol Abuse and Alcoholism

Lorraine Gunzerath *; Dorita Sewell

National Institute of Allergy and Infectious Diseases

Lai Tan *, Diane Adger-Johnson, Susan Schafer, Wallace Robinson, Joyce Woodford, Diane Yerg

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Christine Densmore *, Julia Freeman

National Institute of Child Health and Human Development

Kathleen Wilburn*, Darlene Levenson, Sandra Occhipinti, Yvonne Maddox

---

* 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*, Sue Hamilton, Karen Boone

National Institute of Dental and Craniofacial Research
Margo Adesanya*, Trenita Davis, Maria Canto

National Institute of Diabetes, Digestive and Kidney Disorders
Beth Paterson *, Patricia Robuck, Donna James

National Institute on Drug Addiction
Jack Manischewitz *, Mark Swieter

National Institute of Environmental Health Sciences
Martha Barnes *

National Institute of General Medical Sciences
John Matala *, Alison Cole

National Institute of Mental Health
Mary Lou Prince *, Mary Blehar, William Radcliffe, Pamela Wexler, Tracy Soto

National Institute of Neurological Disorders and Stroke
Mary Ellyn Michel*, Connie Atwell, Gladys Melendez-Bohler

National Institute of Nursing Research
Carole Hudgings *, Robin Gruber

National Library of Medicine
Rita Richey *, Dwight Mowery

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

National Center for Complementary and Alternative Medicine
Jennifer Tisch

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

List of Members, continued...

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

Fogarty International Center
Aron Primack*, Kathleen Michels

Center for Scientific Review
Elliot Postow *

Office of Intramural Research
Alan Sandler

National Center for Minority Health and Health Disparaties
Eric Bailey*, John Ruffin

National Institute of Biomedical Imaging and Bioengineering
Meredith Temple*, Joan Harmon, Mollie Sourwine, Yinka Abu

---

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

Appendix C

Responses to the General Accounting Office (GAO) Report: "Women's Health: NIH Has Increased Its Efforts to Include Women in Research"

GAO/HEHS-00-96, September 2002

Status Report on Actions Taken on General Accounting Office (GAO) Report, "Women's Health: NIH Has Increased Its Efforts to Include Women in Research", GAO/HEHS-00-96, September 2002

This document represents a status report of actions taken by the National Institutes of Health in response to the second recommendation of the May 2000 General Accounting Office Report, "Women's Health: NIH Has Increased Its Efforts to Include Women in Research."

RECOMMENDATION #2

To improve the accuracy of NIH's tracking data on the inclusion of women and minorities, we recommend that the Director of the NIH ensure that the NIH staff who transmit data to the tracking system receive ongoing training on the requirements and purpose of the system.

NIH STATEMENT: The launch of a new electronic database for grant review, management and administration, which would include a computerized system for standardizing and collecting inclusion data, would occur before the end of the calendar year 2000.

CURRENT STATUS:

The NIH population tracking system for monitoring the inclusion of women and minorities in clinical research was successfully deployed in May 2002. This system provides easier data entry and project monitoring for NIH staff, creates clear and timely NIH reports on inclusion data, incorporates the 1997 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). The re-engineered population tracking system continues to be refined based on input from the NIH user community.

Several training efforts have been conducted to assist staff in using the new system. In January 2002, NIH conducted and archived a videocast training session on the updated policies and procedures on sex/gender and minority inclusion. This session was mandatory for all NIH program, grants management and review staff involved in the administration of clinical research. To accompany the training course, a comprehensive training manual explaining the new polices and procedures was developed as a training resource and remains available electronically for all NIH staff. In May 2002, NIH provided a second session for the Center for Scientific Review that highlighted the requirements and issues for scientific review staff.

Also in May, NIH published an on-line users guide and began offering 2-hour demonstrations to accompany the launch of the new system. To date, ten 2-hour sessions have been conducted with one session archived as a videocast session for subsequent staff training. Since July 2002, an additional eight 3-hour, in-depth, hands-on training sessions have been provided to NIH staff. The training materials for the hands-on course will be available electronically to NIH staff in mid-September. Additional demonstration sessions and hands-on training sessions will be offered in Fall 2002/Winter 2003. All training materials are available to NIH staff via http://imacii.nih.gov.

In addition to launching the new system and providing staff training, NIH has been providing outreach to the scientific community to help increase their understanding of the revised inclusion policy and OMB requirements. To date, staff have participated in two NIH Regional Seminar meetings (each involving approximately 400 extramural scientists and administrators), presented to the NIH Clinical Center faculty and students, and developed a resource slide show on the inclusion policy and OMB requirements that can be used by Institute staff when working with the extramural community.

The NIH continues to provide training to intramural and other research investigators through its comprehensive training programs. These ongoing programs include: *Clinical Research Training Course for Intramural Investigators; Introduction to the Principles and Practice of Clinical Research; Principles of Clinical Pharmacology; Ethical and Regulatory Aspects of Human Subjects Research; Computer Based Training for the Protection of Human Subject Research; and Computer Based Training Course for NIH IRB Members*. 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. As a result, a web-based educational module is now available on-line. The curriculums for the Clinical Research Programs provide guidance on the NIH policies related to clinical research and continue to be evaluated.

To capture and report data on women and minorities, the NIH intramural program uses centralized systems within the hospital from which data are abstracted and reported. This information is self-reported by the patient and is centrally collected and entered into the hospital's information systems by the Admission staff at the time of the patient's visit to the Clinical Center. Modifications to the hospital's systems were made to comply with the updated OMB Directive 15, and training was provided to the necessary staff. The data will be analyzed in the near future to determine if there is a need for additional training programs. NIH is currently working on reporting intramural program FY2002 inclusion data and future inclusion data using the new population tracking system.

Status of Activities on GAO Report on Women's Health (GAO/HEHS-00-96, May 2000)			
Activity	***Due Date***	***Status***	***Date Completed***
Notice in NIH Guide to Grants & Contracts - clarifies policy for gender analyses for Phase III clinical trials	*8/1/2000*	Completed - link from Women and Minorities Web Page at: http://grants.nih.gov/grants/funding/women_min/women_min.htm	*8/2/2000*
Language incorporated in NIH solicitations for grant applications and contract proposals (PA/RFA/RFP) indicating requirements for applications and reporting for Phase III clinical trials	*Effective 10/1/2000*	Completed document	*8/2/2000*
A new Terms and Conditions for Awards will be included in all grant, cooperative agreement, & contract awards containing Phase III clinical trials	*Effective 10/1/2000*	Completed document	*8/2/2000*
Guidelines/instructions for reviewers & SRAs developed clarifying the need to review research proposals containing Phase III clinical trials. Documentation required in summary statements addressing adherence to these policies	*10/26/2000*	Completed document http://grants.nih.gov/grants/peer/hs_review_inst.pdf	*02/2001*
Train NIH program & review officials and grants & contracts management staff on	*Fall 2000*	Symposium training session for extramural staff (450) occurred on10/16 on new policies and	*10/16/00*

Status of Activities on GAO Report on Women's Health (GAO/HEHS-00-96, May 2000)			
Activity	***Due Date***	***Status***	***Date Completed***
updated policy for Phase III clinical trials (workshops, presentations at professional meetings & advisory committees; web-site didactic instructions; & on-line Q&A and fact sheets)		procedures regarding human subjects. An additional 400 individuals viewed the symposium in satellite centers and 175 additional NIH staff utilized a VideoCast system.	
		An additional training session regarding **a Grants Policy Update: Humans and Animals** targeting extramural and intramural research, program and grants management, and review staff.	*12/11/00*
		Video tapes and web-video access from the 10/16 and 12/11 training are available to NIH staff.	
		Frequently Asked Questions document.	*7/5/2001*
		Training of Extramural and Intramural staff at December 2000 Full Tracking and Inclusion Committee Meeting.	*12/11/00*
		Sex/Gender and Minority Inclusion in Clinical Research: Staff Training Workshop (over 400 participants; videocast and archived; available online to NIH staff.	*1/2/2002*
Intramural Training on Updated Policies and Population Tracking System	Ongoing	Required for all PI's. The NIH Clinical Center continues to provide training to intramural and other PI through comprehensive training programs; Computer-based	Revised: Spring/Fall 2002

Status of Activities on GAO Report on Women's Health (GAO/HEHS-00-96, May 2000)			
Activity	***Due Date***	***Status***	***Date Completed***
		training; web-based modules available on-line.	
ORWH & OER work together to ensure NIH staff are well-informed about data collection requirements of current tracking system	No end date	Continuing	Ongoing
NIH develop specific tracking/inclusion module to interface w/ IMPAC2 system.	12/31/2000	System Deployed	May 2002
NIH staff training on tracking system module to interface w/ IMPAC2 system.	6/2002	NIH wide system training June 2002 - (10) 2 hr demonstration sessions (archived and videocast) - (8) 3 hr hands-on training sessions	Ongoing
Training on current *NIH Tracking System* to members of *Full Tracking & Inclusion Committee*.	12/11/2000	OER conducted training on the current tracking system at the 12/11 *Full Tracking & Inclusion Committee* meeting.	12/11/2000

Appendix D

Internet Homepage:

Inclusion of Women and Minorities Policy Implementation

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

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

Inclusion of Women and Minorities 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 E

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

(Amended, October, 2001)

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

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

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

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

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

I. LEGISLATIVE BACKGROUND

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

The statute states that:

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

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

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

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

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

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

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

The statute speaks specifically to outreach and states that:

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

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

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

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

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

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

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

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

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

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

II. POLICY

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

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

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

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

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

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

1. Prior Studies Support the Existence of Significant Differences

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

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

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

2. Prior Studies Support No Significant Differences

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

3. Prior Studies Neither Support nor Negate Significant Differences

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

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

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

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

III. ROLES AND RESPONSIBILITIES

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

1. NIH Staff

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

2. Principal Investigators

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

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

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

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

Asked Questions document, are located at the following URL:
http://grants.nih.gov/grants/funding/women_min/women_min.htm

3. Institutional Review Boards (IRBs)

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

4. Peer Review Groups

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

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

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

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

Or contact:

National Institutes of 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

Dr. Julia Freeman
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building
Building 45, Room 5AS19F
Bethesda, MD 20892
Telephone: (301) 594-4543
Email: freemanj@ep.niams.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. Julie Gulya
National Institute on Deafness and Other Communication Disorders
Executive Plaza South
6120 Executive Boulevard, Room 400D-7
Rockville, MD 20892
Telephone: (301) 435-4085
Email: gulyaj@ms.nidcd.nih.gov

Dr. Norman S. Braveman
National Institute on Dental and Craniofacial Research
Natcher Building
Building 45, Room 4AN24C
Bethesda, MD 20892
Telephone: (301) 594-2089
Email: BravemanN@de45.nidr.nih.gov

Dr. Robert Hammond
National Institute of Diabetes and Digestive and Kidney Diseases
2 Democracy Boulevard, Room 715
Bethesda, MD 20892

Telephone: (301) 594-8834
Email: hammondr@extra.niddk.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

Dr. Richard Nakamura
National Institute of Mental Health
Neuroscience Building
6001 Executive Boulevard, Room 8235
Bethesda, MD 20852
Telephone: (301) 443-3675
Email: rnakamur@mail.nih.gov

Dr. Mary Ellen Michel
National Institute of Neurological Disorders and Stroke
Neuroscience Building
6001 Executive Boulevard, Room 2227
Bethesda, MD 20892- 9525
Telephone: (301) 496-1447
Email: michelm@ninds.nih.gov

Dr. Mark Guyer
National Human Genome Research Institute
Building 31
31 Center Drive, Room B2B07
Bethesda, MD 20892

Telephone: (301) 496-7531
Email: guyerm@exchange.nih.gov

Dr. Carole Hudgings
National Institute of Nursing Research
Natcher Building
45 Center Drive, Room 3AN-12
Bethesda, MD 20892
Telephone: (301) 594-5976
Email: carole_hudgings@nih.gov

Dr. Christine Goertz
National Center for Complementary and Alternative Medicine
Building 31
31 Center Drive, Room 5B-58
Telephone: (301) 402-1030
Email: GoertzC@od.nih.gov

Dr. Geoffrey Cheung
National Center for Research Resources
Rockledge Centre I
6705 Rockledge Dr, Rm 6118
Bethesda, MD 20817
Telephone: (301) 435-0768
Email: cheungg@ncrr.ncrr.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

Dr. Meredith Temple
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Boulevard, Room 980
Bethesda, MD 20892
Telephone: (301) 451-4792
Email: templem@mail.nih.gov

Dr. Eric Bailey
National Center for Minority Health and Health Disparities
2 Democracy Boulevard, Suite 800
Bethesda, MD 20817
Telephone: (301) 402-1366
Email: baileye@od.nih.gov

Appendix F

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

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

Release Date: August 8, 2001

NOTICE: NOT-OD-01-053

National Institutes of Health

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

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

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

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

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

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

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

Ethnic Categories:

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

Not Hispanic or Latino

Racial Categories:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Annual Progress Reports (type 5) and Competing Supplement Applications

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

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

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

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

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

III. Frequently Asked Questions

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

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

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

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

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

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

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

Neither the Targeted/Planned Enrollment 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

Dr. Julia Freeman

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building
Building 45, Room 5AS19F
Bethesda, MD 20892
Telephone: (301) 594-4543
Email: freemanj@ep.niams.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. Julie Gulya
National Institute on Deafness and Other Communication Disorders
Executive Plaza South
6120 Executive Boulevard, Room 400D-7
Rockville, MD 20892
Telephone: (301) 435-4085
Email: gulyaj@ms.nidcd.nih.gov

Dr. Norman S. Braveman
National Institute on Dental and Craniofacial Research
Natcher Building
Building 45, Room 4AN24C
Bethesda, MD 20892
Telephone: (301) 594-2089
Email: BravemanN@de45.nidr.nih.gov
Dr. Robert Hammond
National Institute of Diabetes and Digestive and Kidney Diseases
2 Democracy Boulevard, Room 715
Bethesda, MD 20892
Telephone: (301) 594-8834
Email: hammondr@extra.niddk.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.gov

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

Dr. Richard Nakamura
National Institute of Mental Health
Neuroscience Building
6001 Executive Boulevard, Room 8235
Bethesda, MD 20852
Telephone: (301) 443-3675
Email: rnakamur@mail.nih.gov

Dr. Mary Ellen Michel
National Institute of Neurological Disorders and Stroke
Neuroscience Building
6001 Executive Boulevard, Room 2227
Bethesda, MD 20892- 9525
Telephone: (301) 496-1447
Email: michelm@ninds.nih.gov

Dr. Mark Guyer
National Human Genome Research Institute
Building 31
31 Center Drive, Room B2B07
Bethesda, MD 20892
Telephone: (301) 496-7531
Email: guyerm@exchange.nih.gov

Dr. Carole Hudgings
National Institute of Nursing Research
Natcher Building
45 Center Drive, Room 3AN-12
Bethesda, MD 20892
Telephone: (301) 594-5976
Email: carole_hudgings@nih.gov

Dr. Christine Goertz
National Center for Complementary and Alternative Medicine
Building 31
31 Center Drive, Room 5B-58
Telephone: (301) 402-1030
Email: GoertzC@od.nih.gov

Dr. Geoffrey Cheung
National Center for Research Resources
Rockledge Centre I
6705 Rockledge Dr, Rm 6118
Bethesda, MD 20817
Telephone: (301) 435-0768
Email: cheungg@ncrr.ncrr.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

Dr. Meredith Temple
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Boulevard, Room 980
Bethesda, MD 20892
Telephone: (301) 451-4792
Email: templem@mail.nih.gov

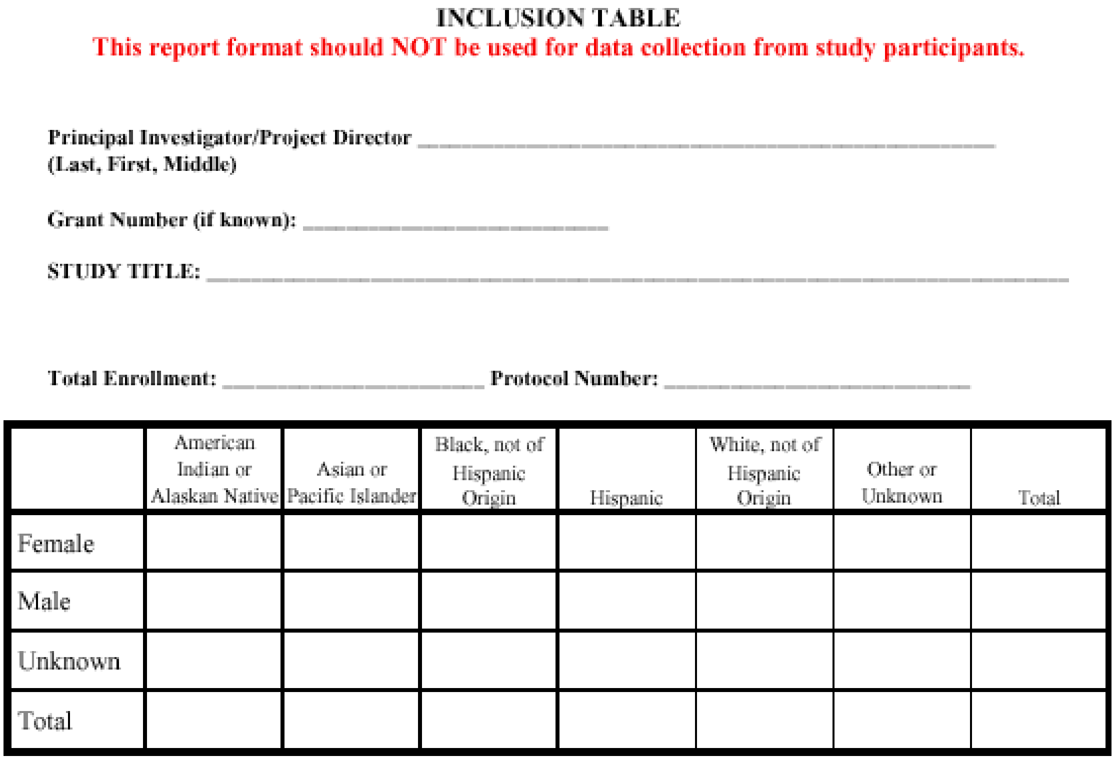
Dr. Eric Bailey
National Center for Minority Health and Health Disparities
2 Democracy Boulevard, Suite 800
Bethesda, MD 20817
Telephone: (301) 402-1366
Email: baileye@od.nih.gov

APPENDIX G

NIH Inclusion Tables for Target and Enrollment Data

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

OLD TABLE - TARGET/ENROLLMENT DATA



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 - TARGET DATA

●

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

Targeted/Planned Enrollment Table

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

Study Title:

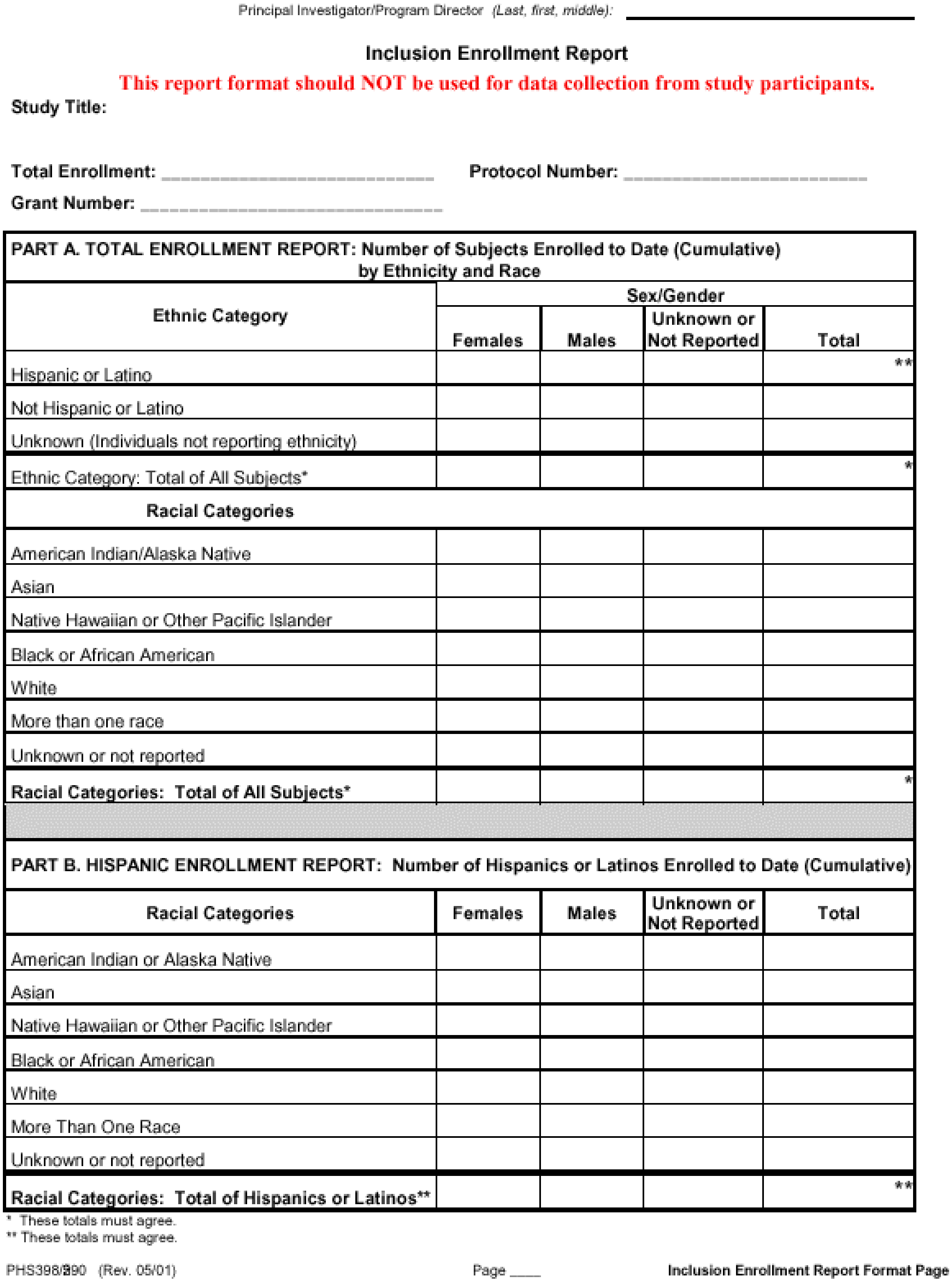
Total Planned Enrollment:

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

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

NEW TABLE - ENROLLMENT DATA

-



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

	Sex/Gender			
Ethnic Category	**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**