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

Comprehensive Report: Tracking of Human Subjects Research Reported in FY 2002 and FY 2003

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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.

Implementation of Training Activities Ensuring Compliance with the Policy

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. 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.

- 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.

- 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.

- 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.

- 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.

Communication and Outreach Efforts to the Scientific Community

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

- 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. http://grants.nih.gov/grants/funding/women_min/training/index.htm

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

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

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

Monitoring Compliance: Extramural and Intramural Population Data Analysis

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

NIH has monitored aggregate demographic data for study populations through an 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). Following the implementation of the population tracking module, an *eRA Population Tracking User Group* consisting of representatives from several ICs, was formed to evaluate the new system, recommend improvements and modifications, and provide feedback related to system use. 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.

- Since July 2002, 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.

The aggregate data enable the NIH to monitor inclusion in order to formulate more specific questions about gaps in enrollment and to design studies to respond to those questions. Aggregate data are reported annually by Fiscal Year (FY).

New Method Implemented Beginning with Data for Funding in FY2001 and Reported in FY 2002

The data tables for FY 2002 (reported in FY 2003) are produced from the current NIH population tracking system that stores and reports data based on the fiscal year in which data are reported to NIH as part of the annual progress report. The FY 2002 (reported in FY 2003) tables reflect data submitted to NIH in FY 2003 as part of the annual progress report and reflects cumulative enrollment through FY 2002 and through the time when the progress report was submitted to NIH. In addition, the FY 2002 (reported in FY 2003) tables describe data using both the 1977 and 1997 OMB standards for reporting data on race and ethnicity. The 1997 OMB standards involve a number of changes including: collecting and reporting information on ethnicity and race separately; using the new definitions and categories for ethnicity and race; allowing respondents the option of selecting more than one race; and reporting the number of respondents who selected more than one race, as well as the number selecting only one racial category.

The introduction of the 1997 OMB reporting format does not allow aggregation of ethnic and racial data with similar data collected under the 1977 OMB standards because the categories and methods for collecting the data are fundamentally different. Also, the FY 2002 (reported in FY 2003) data reflect current changes in the standardization of definitions and business rules across the NIH for improving the data entered in the population tracking system. While this transition period makes comparisons with prior FY data difficult, implementation of these changes will improve the consistency and comparability with future reporting.

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.

Conclusion

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

References

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

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

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

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.

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

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

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

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

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

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

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

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

Aggregate Enrollment Data Tables For Extramural and Intramural Research Protocols

Funded in Fiscal Year 2001 & Reported in FY 2002
Funded in Fiscal Year 2002 & Reported in FY 2003

Pages 15-42 available at
http://www4.od.nih.gov/orwh/DataTables_FY2002-2003.pdf

Summary Report of NIH Inclusion Data

NIH Aggregate Extramural and Intramural Population Data
Funded in FY 2001 & Reported in FY 2002 and Funded in FY 2002 & Reported in FY 2003

Tables 1 to 10 provide aggregate enrollment data for extramural and intramural research protocols funded in FY 2002 and FY 2003. Previous inclusion reports and aggregate enrollment figures for FY 1994 through FY2002 for women, men and minority groups may be found on the ORWH website at http://od.nih.gov/orwh/inclusion.html.

Analysis of the FY 2001 (reported in FY 2002) and FY 2002 (reported in FY 2003) inclusion data show that substantial numbers of women, non-minority men, and minorities have been included as research subjects in Phase III clinical trials and other human subject research studies, in both intramural and extramural programs. Overall, approximately 94% of applications involving human subjects met the inclusion requirements as submitted to the Initial Review Group [see Table A]. Of those selected for award in FY 2002, more than 96% were determined to have met the inclusion requirements as submitted. All of the remaining 4% of applications were required to address and to 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 FY 2002 (reported in FY 2003) show that approximately 55.8% of the subjects were women. Of the 628 extramural Phase III research protocols that continue to report following the 1977 OMB standards, minority representation was highest for Black (not Hispanic) subjects (11.6%) and lowest for American Indian/Alaska Native at 0.4%. Hispanic subjects comprised approximately 10%, Asian/Pacific Islander subjects were 1.84% and White (not Hispanic) subjects were 77.2%. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards and therefore, no data were reported in these categories.

Accordingly, 205 extramural Phase III research protocols submitted data following the 1997 OMB standards for reporting race and ethnicity. Minority representation by race was highest for Black subjects (28.23%) and lowest for Hawaiian/Pacific Islander (0.2%). Asian subjects comprised 3.99% of participants, American Indian/Alaska Native subjects were 0.51% and White subjects were 55.4%. 1.54% of the participants identified *More Than One Race* for their racial category. Of the 205 extramural Phase III research protocols designating an ethnicity, 76.9% of the subjects identified a racial category and an ethnicity of not Hispanic. Whereas, 10% identified a racial category and an ethnic category of Hispanic/Latino. 13.1% participants identified a racial category but did not report an ethnicity or Unknown ethnicity.

Over 12 million subjects were included in the research projects covered by the tracking system in FY 2002 (reported in FY 2003). A snapshot of the aggregate enrollment data [Table 1] shows that approximately 60.7% of the subjects were women, approximately 38.3% were men, and approximately 0.9% did not identify a sex/gender. Extramural studies funded in FY 2002 (reported in FY2003) [Table 2] show that approximately 68.1% of the subjects were women, approximately 31.2% were men, and approximately 0.7% did not provide sex/gender identification. Overall, the number of women participants decreased by 7.4%, the number of men increased by 7.1% and the number of subjects that did not identify their sex/gender increased by 0.2% comparatively. However, when sex-specific studies were excluded for FY 2002 (reported in FY 2003), the proportions of subjects were proportional to the percentages of the general population, 50.6% women and 48.1% men respectively.

Changes in percentages between FY 2002 and FY 2003 were attributable to the ending of previously reported studies where enrollments ranged from 20,000 to 300,000 participants per study. Although other new studies have been launched in FY 2002, enrollment for these new studies is just beginning. Another reason for the fluctuations between FY 2002 and FY 2003 enrollment percentages is the improved reporting and corrections of errors by investigators. Recognizing that information on sex/gender and ethnicity/race is obtained voluntarily from study participants, some participants will elect not to report this information, i.e. the data are recorded as "Unknown."

Approximately 1.8 million subjects were included in the tracking system from intramural research projects in FY 2002 (reported in FY2003). Intramural studies funded and reported in FY 2003 [Table 9] show that approximately 47.5% of intramural subjects were women and approximately 51.6% were men. Among minority subjects, representation in intramural studies was highest for Asian subjects at 10.5% and lowest for American Indian/Alaskan native subjects (1.01%) following the 1977 OMB standards. Hispanic subjects represented approximately 3.12%; Black subjects 5.65%; and White (not Hispanic) subjects represented 40.5% of the intramural research study population following the 1977 OMB standards. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the 1977 OMB standards and therefore, no data were reported in these categories.

Likewise, 156 intramural research protocols submitted data following the 1997 OMB standards for reporting race and ethnicity. Minority representation was highest for Black subjects (17.34%) and lowest for Hawaiian/Pacific Islander subjects (0.03%). Asian subjects comprised 5.81% of participants and White subjects were 70.5% of the intramural participants. Of the 156 intramural research protocols designating an ethnicity, 5.26% identified themselves as Hispanic/Latino. 92.8% of the subjects identified their ethnicity as not Hispanic and 1.91% participants identified a racial category but did not report an ethnicity or Unknown ethnicity.

Aggregate data tables available at http://www4.od.nih.gov/orwh/DataTables_FY2002-2003.pdf

APPENDICES

Appendix A

Explanation of Sex and Minority Codes

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

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

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

Appendix B

NIH Tracking and Inclusion Committee Members

- Full Committee

NIH Tracking and Inclusion Committee
List of Members
Year 2002-2003 (updated 3/30/2004)

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
Carlos Caban*, Melissa Hirsch, Dan Hall
Office of Acquisition, Management and Procurement
Zaiga Tums, Barbara Levy, Joann Wingard

National Cancer Institute
Margaret Holmes*, Diane Bronzert, Marilyn Gaston, Joe Harford, 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 DeLeon*, Susan Saylor

National Institute on Aging
Miriam Kelty *, Karen Bashir

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

National Institute of Allergy and Infectious Diseases
Marie Parker*, Lai Tan , Diane Adger-Johnson, Susan Schafer, Christine Beachley, Joyce Woodford, Diane Yerg, Martin Gutierrez

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Charisse Lamar*, Julia Freeman

National Institute of Child Health and Human Development
Michael Whalin,*, Sandra Occhipinti

* 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, Lana Shekim

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

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

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
Michelle Parker*, Catherine Roca, Mary Lou Prince, Ernesto Marquez, Pamela Wexler, Sue Kennel

National Institute of Neurological Disorders and Stroke
Mary Ellyn Michel*, Connie Atwell, Frances Yee

National Institute of Nursing Research
Janice Phillips*, Christian Shaw

National Library of Medicine
Rita Richey *, Dwight Mowery

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

National Center for Complementary and Alternative Medicine
April Bowers*

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* 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
Laura Rowe*, Aron Primack

Center for Scientific Review
Anita Miller Sostek*

Office of Intramural Research
Alan Sandler

National Center for Minority Health and Health Disparities
Eric Bailey*, John Ruffin, Tommy Broadwater

National Institute of Biomedical Imaging and Bioengineering
Meredith Temple*, Tinera Fobbs, Yinka Abu

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

Appendix C

Internet Homepage:

Inclusion of Women and Minorities Policy Implementation

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Office of Extramural Research

Inclusion of Women and Minorities Policy Implementation

Current Policy Documents and References:

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

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

Historical Documents and References:

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

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

Appendix D

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

(Amended, October, 2001)

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

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

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

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

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

I. LEGISLATIVE BACKGROUND

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

The statute states that:

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

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

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

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

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

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

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

The statute speaks specifically to outreach and states that:

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

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

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

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

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

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

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

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

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

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

II. POLICY

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

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

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

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

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

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

1. Prior Studies Support the Existence of Significant Differences

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

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

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

2. Prior Studies Support No Significant Differences

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

3. Prior Studies Neither Support nor Negate Significant Differences

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

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

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

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

III. ROLES AND RESPONSIBILITIES

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

1. NIH Staff

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

2. Principal Investigators

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

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

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

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

3. Institutional Review Boards (IRBs)

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

4. Peer Review Groups

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

- to evaluate the proposed plan for the inclusion of minorities and both genders for appropriate representation or to evaluate the proposed justification when representation is limited or absent,

- to evaluate the proposed exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect to the health of the subjects,
- to evaluate the proposed exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect to the purpose of the research,
- to determine whether the design of clinical trials is adequate to measure differences when warranted,
- to evaluate the plans for valid analysis for NIH-defined Phase III clinical trials,
- to evaluate the plans for recruitment/outreach for study participants, and

- to include these criteria as part of the scientific assessment and evaluation.

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

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

Or contact:

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

5. NIH Advisory Councils

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

6. Institute/Center Directors

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

7. NIH Director

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

IV. DEFINITIONS

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

A. Clinical Research

Clinical research is defined as:

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

B. NIH-defined Clinical Trial

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

C. Valid Analysis

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

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

D. Significant Difference

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

E. Racial and Ethnic Categories

1. Minority Groups

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

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

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

The following definitions apply for ethnic categories.

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

Not Hispanic or Latino

The following definitions apply for racial categories.

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

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

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

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

2. Majority Group

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

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

3. Subpopulations

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

F. Outreach Strategies

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

V. NIH CONTACTS FOR MORE INFORMATION

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

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

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Appendix E

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

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

Release Date: August 8, 2001

NOTICE: NOT-OD-01-053

National Institutes of Health

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

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

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

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

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

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

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

Ethnic Categories:

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

Not Hispanic or Latino

Racial Categories:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Annual Progress Reports (type 5) and Competing Supplement Applications

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

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

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

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

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

III. Frequently Asked Questions

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

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

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

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

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

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

Latino number reported in Part A of the “Inclusion Enrollment Report.” Footnotes in the tables clearly identify which numbers must be the same.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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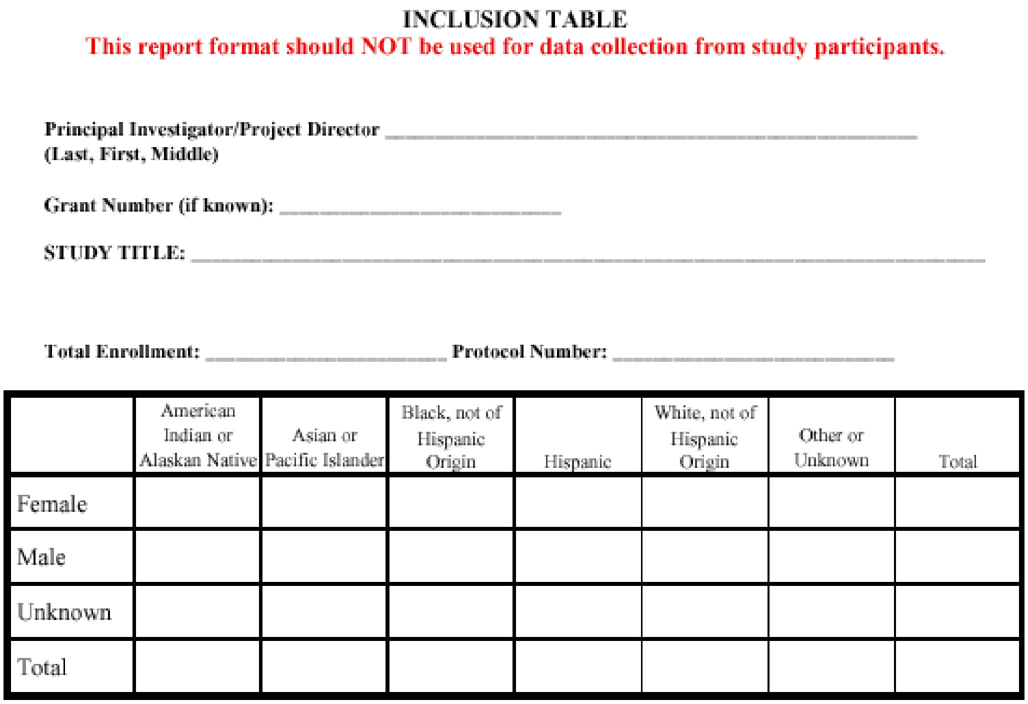
APPENDIX F

NIH Inclusion Tables for Target and Enrollment Data

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

Old Table for Target & Enrollment Data Collection



INCLUSION TABLE

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

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

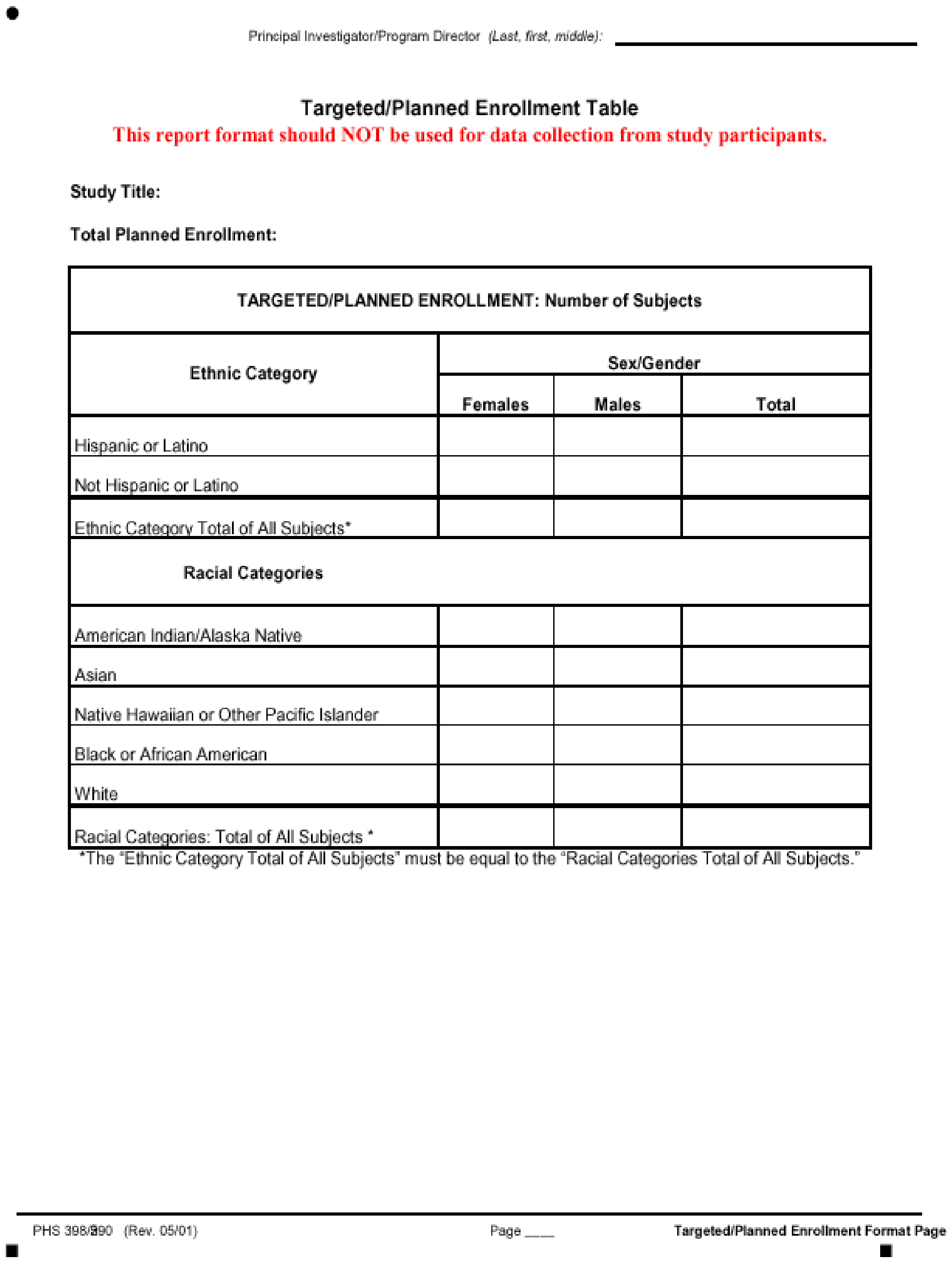
Grant Number (if known): ____________________

STUDY TITLE: ____

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

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

New Table for Target Data Collection



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

Targeted/Planned Enrollment Table

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

Study Title:

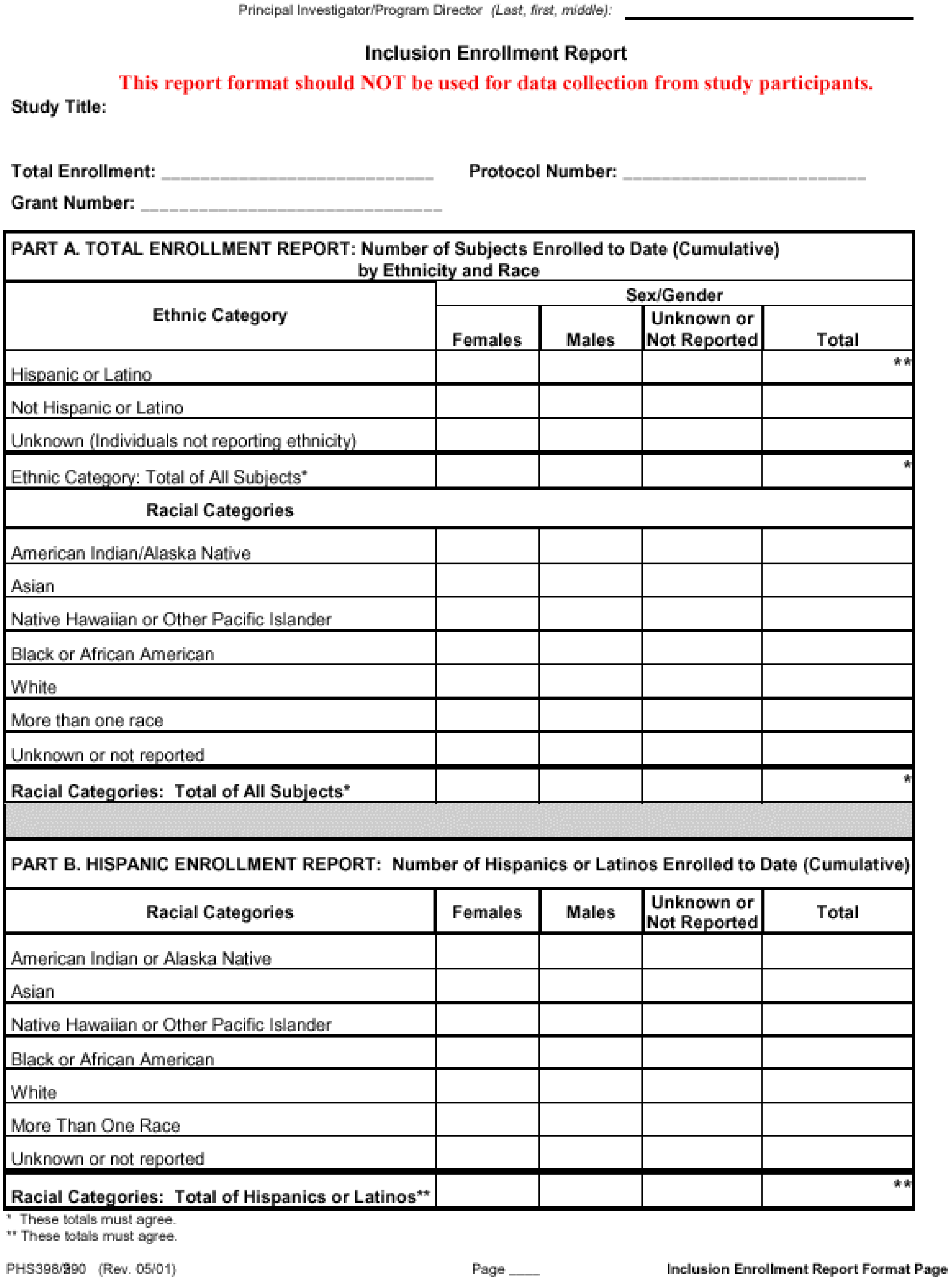
Total Planned Enrollment:

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

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

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

New Table for Enrollment Data Collection

- 

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

Inclusion Enrollment Report

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

Study Title:

Total Enrollment: ____________________________ **Protocol Number:** _________________________

Grant Number: _______________________________

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

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

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

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

* These totals must agree.
** These totals must agree.

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