

IMPLEMENTATION OF THE NIH GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

Comprehensive Report
(Fiscal Year 1997 Tracking Data)

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

In 1994, the NIH revised its inclusion policy to meet the specific mandate of the NIH Revitalization Act of 1993 (PL 103-43) 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 human subject 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 volunteers in clinical studies.

Revised inclusion guidelines developed in response to this law were published in the *Federal Register* in March 1994, and they became effective in September 1994 for proposals submitted after June 1, 1994.

Strategies to ensure that the implementation of the revised guidelines is uniform 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 Institutes and Centers (IC). This trans-NIH committee meets on a regular basis, focusing on consistent and widespread adherence to the NIH guidelines by all the institutes and centers. Working in collaboration with the Office of Extramural Research, the Office of Intramural Research, and other components of the NIH, the Office of Research on Women's Health coordinates the activity of developing and establishing data collection and reporting methodologies to ensure uniform standards and definitions in the reporting of data on the participation of women and minority volunteers in NIH-funded research.

To ensure universal adherence to the new inclusion guidelines, NIH conducted extensive training on the revised inclusion guidelines for more than 1,000 NIH staff members with review, program, grants management, or contract management responsibilities. NIH staff, in turn, explained the requirements to applicants, reviewers, and other members of the research community. NIH staff members, reviewers, and applicants received written guidance about the requirements. This guidance outlined in great detail the circumstances under which it may be acceptable to use study populations deficient in women or minority participants, pointing out that the justification must be compelling and the scientific objectives of the research must be maintained. Training was especially important in response to 1990 findings by the U.S. General Accounting Office (GAO) that an earlier policy was inconsistently applied and had not been well communicated or understood within the NIH or in the research community.

Recognizing the importance of both recruitment and retention of human subject volunteers, NIH issued an outreach notebook that outlines elements of outreach processes, offers practical suggestions, and provides references to additional sources of information. This outreach notebook also includes the full text of the 1994 implementation guidelines as well as a questions and answers document which was prepared in order 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."

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. For example, 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.

The policy and procedures for meeting the new requirements have been fully implemented. Studies that do not meet the standards are identified through the scientific review process. The level of compliance is high, and activities will continue to ensure adherence to the revised guidelines.

NIH is now able to monitor demographic data for study populations on an NIH-wide basis through a computerized tracking system. Analysis of data for which NIH-wide data are available (FY1997) show that substantial numbers of both women and minorities have been included as research subjects in Phase III clinical trials and other human subject research studies, in both intramural and extramural programs. During FY1997, more than 93% of applications involving human subjects met the inclusion requirement as submitted [Table 1].

Aggregate enrollment data for extramural Phase III clinical trials funded in FY1997 show that approximately 74.8% of the subjects were women. Among minority subjects,¹ representation in Phase III clinical trials [Table 97D] was highest for Black (not Hispanic) subjects (14%) and lowest for American Indians/Alaskan Natives subjects (1.6%). Asian/Pacific Islanders subjects were 1.7% of the extramural Phase III subjects; Hispanic subjects were 5.4%; and White (not Hispanic) subjects were 75.1%. Over six million subjects were included in the research for which data were collected in the tracking system from among all extramural research active in FY1997. This snapshot of aggregate enrollment data for FY1997 extramural studies [Table 97A] shows that approximately 62% of the subjects were women, approximately 37% were men, and approximately 1% were not identified by sex/gender.

Substantial numbers of women and minorities were also included in NIH intramural protocols conducted at the Warren G. Magnuson Clinical Center in FY1997 [Table 97G]. Data showed 49.6% of intramural subjects were women and 50.4% were men. Among minority subjects, representation in intramural protocols conducted at the Clinical Center was highest for Black (not Hispanic) subjects (11%) and lowest for American Indian/Alaskan native subjects (0.1%). Asian/Pacific Islander subjects were 4.3% of the subjects in this intramural research; Hispanic subjects were 3.2%; and White (not Hispanic) subjects were 80.1%.

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

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

The aggregate data enable the NIH to measure inclusion in order to formulate more specific questions about gaps in enrollment, to design studies to respond to those questions that allow for longitudinal examination of trends and continued monitoring of compliance. An application that fails to meet the standards for inclusion receives an unacceptable gender or minority code, which results in an administrative bar-to-funding (Appendix A). For most of the awards that were initially barred, the applicants were able to remedy the deficiencies found during initial review by providing additional information. In some instances, studies may have met the inclusion requirement but the justification was not apparent to the reviewers. In such cases, it is each applicant's responsibility to submit a complete research plan and to provide convincing justification before review.

NIH's administrative procedures allow further consideration of such applications during the second level of review. The program staff has the flexibility to work with an applicant and resolve problems within the time constraints of the review-council cycle. In some cases, the program staff may find lack of inclusion in an individual study to be justified if that same scientific question is addressed elsewhere for other populations so that, when viewed in their entirety, the combined studies fulfill the inclusion requirement. Similar procedures are in place for projects funded through contracts.

In compliance with the provisions of the NIH Revitalization Act, the Advisory Council of each IC has reviewed IC procedures for implementation of NIH guidelines for the inclusion of women and minorities in clinical research. In 1999, Advisory Councils reported that all ICs were in compliance with the NIH Implementation Guidelines, which included analysis of FY1997 data.

Reports from the Advisory Councils,² describing individual IC procedures for the implementation of the guidelines and data on inclusion of women and minorities in human subject research included the following observations:

- Scientific Review Groups (SRGs) and scientific program staff were found to be diligent and rigorous in implementing the policies and procedures for meeting the requirements of the NIH guidelines.
- Institute review, program, and grants management staff have attended the extensive training sessions on the inclusion guidelines conducted by NIH. Institute staff, in turn, explain the requirements to applicants, reviewers, and other members of the research community.
- Health scientist administrators (program) review progress reports for funded grants to ensure continued compliance as approved in the initial grant application.
- Advisory Council members continue to be kept aware of the inclusion requirements. During Council meetings, Advisory Council members are informed of concerns regarding the inclusion requirements identified in the review of grant applications.

Inclusion of Women and Minorities in Clinical Research - Future Directions

Future endeavors include efforts to expand the analysis of demographic data collected for clinical studies in order to determine ongoing and changing trends in enrollment and assess their meaning. Target data for Phase III Clinical Trials are being collected, and ways to assess this data in a meaningful manner are under discussion.

²Copies of certifications are available in the Office of the Director, NIH and the Office of Research on Women's Health.

The issue of reporting foreign populations has made clear the occasional need to develop points of clarification for tracking population data. More than two-thirds of the ICs that fund research involving foreign populations reported them the same way they did U.S. populations, i.e., a breakdown by gender/ethnicity in the population matrix found in the PHS 398 form. Of the remainder, some reported them as other/unknown, others used an exception code, and still others are not funding studies with foreign subjects.

The Application for a PHS Grant (Form PHS 398) states, “The NIH policy is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.” Therefore:

- Tracking foreign populations ensures compliance with the policy.
- Tracking foreign populations provides unique opportunities to collect data on subpopulations where knowledge gaps exist. In fact, subpopulations are the focus of many current foreign grants.
- Reporting foreign populations as other/unknown or excluding them could create the impression that NIH is intentionally skewing data to hide non-compliance with the policy.

The NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research state:

For foreign awards, the NIH policy on inclusion of women in research conducted outside the U.S. is the same as that for research conducted in the U.S.

However, with regard to the population of the foreign country, the definition of the minority groups may be different than 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.

These issues were resolved with a decision to use a flag to identify foreign populations in the NIH Tracking System. This would provide flexibility in reporting aggregate data: domestic data alone, domestic and foreign data combined, or foreign data alone.

When aggregate data includes foreign participants, it is now recommended that reports contain an asterisk and footnote. The footnote should state that the data include subjects from foreign countries; therefore, it cannot be determined with complete accuracy that demographic classifications on foreign participants correspond exactly with minority classifications used for U.S. subjects.

ORWH and the NIH will also continue to meet new challenges related to the recruitment and retention of women and minorities in clinical studies, particularly with regard to expanded community outreach and legal, ethical, and social implications. Issues involving special populations of women will continue to receive attention. Finally, ORWH will work with the ICs and broader scientific communities to determine how to better facilitate sex and gender analysis of data from NIH supported research, as required by the NIH Revitalization Act of 1993, in published reports of research outcomes.

**Table 1. Level of Compliance with Inclusion Policy in New Extramural Grant Applications
as Assessed During Scientific Peer Review**

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

Table 2. Extramural Competing Awards that Required the Lifting of a Bar-To-Funding

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

**Table 4A. Inclusion by Sex in All Research Studies
Active in FY1994**

	Extramural Studies		Intramural Studies
	Phase III trials**	Other clinical research***	(On Site)
Protocols reporting women only	96	192	121
Protocols reporting men only	14	96	130
Protocols reporting both women and men	334	1,566	492
Protocols involving men, women and Unknown***	92	80	
Sex composition reported as Unknown	9	26	
Protocols reporting men and Unknown	8	3	
Protocols reporting women and Unknown	10	2	
Early Stage studies where enrollment data has not yet been collected	35	329	474
Data Not Available	8	92	0
Totals	606	2,386	1,217

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

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

**** Many studies may be generic.

Overall data is incomplete.

**Table 4B. Inclusion by Sex in All Research Studies
Active in FY1995**

	Extramural Studies		Intramural Studies
	Phase III trials**	Other clinical research***	(On Site)
Protocols reporting women only	89	582	121
Protocols reporting men only	14	241	113
Protocols reporting both women and men	350	3,248	470
Protocols involving men, women and Unknown****	105	310	
Sex composition reported as Unknown	5	84	
Protocols reporting men and Unknown	7	10	
Protocols reporting women and Unknown	9	18	
Early Stage studies where enrollment data has not yet been collected	39	1,404	513
Data Not Available	12	335	0
Totals	630	6,232	1,217

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

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

**** Many studies may be generic.

**Table 4C. Inclusion by Sex in All Research Studies
Active in FY1996**

	Extramural Studies		Intramural Studies
	Phase III trials**	Other clinical research***	On-site
Protocols reporting women only	29	603	118
Protocols reporting men only	10	182	123
Protocols reporting both women and men	166	3,406	457
Protocols involving men, women and Unknown****	14	245	
Sex composition reported as Unknown	0	72	
Protocols reporting men and Unknown	0	5	
Protocols reporting women and Unknown	1	12	
Early Stage studies where enrollment data has not yet been collected	58	1,307	393
Data Not Available	11	235	0
Totals	289	6,067	1,091

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

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

**** Many studies may be generic.

**Table 4D. Inclusion by Sex in All Research Studies
Funded in FY1997***

	Extramural Studies		Intramural Studies
	Phase III trials**	Other clinical research***	On-site
Protocols reporting women only	45	689	98
Protocols reporting men only	7	232	92
Protocols reporting both women and men	181	3,606	450
Protocols involving men, women and Unknown****	8	209	
Sex composition reported as Unknown	5	65	
Protocols reporting men and Unknown	1	3	
Protocols reporting women and Unknown	0	3	
Early Stage studies where enrollment data has not yet been collected	51	1,295	446
Data Not Available	18	264	0
Totals	316	6,366	1,086

*Note change in data collection for FY1997 to include research studies funded in FY97.

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

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

**** Many studies may be generic.

Table 4D-1 Examples of Single Sex Extramural Research Studies

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

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

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

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

**Table 97A. Aggregate Enrollment Data for All Extramural Research Protocols
Funded in FY1997**

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	42,502	1.1%	577,432	15.4%	647,444	17.2%	290,735	7.7%	1,980,881	52.7%	220,332	5.9%	3,759,326	61.9%
Male	28,072	2.9%	292,246	12.9%	384,330	17.0%	195,618	8.7%	1,212,955	53.7%	144,418	6.4%	2,257,639	37.1%
Unknown	432	0.7%	1,185	1.9%	3,533	5.8%	3,945	6.5%	20,157	33.0%	31,882	52.2%	61,134	1.0%
Total	71,006	1.6%	870,863	14.3%	1,035,307	17.0%	490,298	8.1%	3,213,993	52.9%	396,632	6.5%	6,078,099	100.0%

Number of Protocols: 6,799

Comments:

More females (3,759,326 or 61.9%) than males (2,257,326 or 37.1%) are enrolled in aggregate Extramural Research protocols.

Largest identified racial group is White, non-Hispanic at 52.9%.

Largest identified racial minority group is Black, non-Hispanic at 17%.

Smallest identified racial minority group is American Indian/Alaskan Natives at 1.6%.

**Aggregate Enrollment Data for Extramural Research Protocols
Funded in FY 1997**

Table 97B. Distribution of Participants (Numbers)

	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	42,502	577,432	647,444	290,735	1,980,881	220,332	3,759,326
Male	28,072	292,246	384,330	195,618	1,212,955	144,418	2,257,639
Unknown	432	1,185	3,533	3,945	20,157	31,882	61,134
Total	71,006	870,863	1,035,307	490,298	3,213,993	396,632	6,078,099

Table 97C. Distribution of Participants (Percentage)

	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	1.1%	15.4%	17.2%	7.7%	52.7%	5.9%	61.9%
Male	1.2%	12.9%	17.0%	8.7%	53.7%	6.4%	37.1%
Unknown	0.7%	1.9%	5.8%	6.5%	33.0%	52.2%	1.0%
Total	1.2%	14.3%	17.0%	8.1%	52.9%	6.5%	100.0%

**Table 97D. Aggregate Enrollment Data for Extramural Phase III Protocols
Funded in FY1997**

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	2,902	1.3%	4,490	2.0%	26,402	11.6%	10,013	4.4%	181,603	79.5%	3,007	1.3%	228,417	74.8%
Male	2,127	2.9%	834	1.1%	16,256	21.9%	6,423	8.6%	47,829	64.3%	920	1.2%	74,389	24.3%
Unknown	1	0.0%	0	0.0%	147	5.4%	4	0.1%	102	3.8%	2,451	90.6%	2,705	0.9%
Total	5,030	1.6%	5,324	1.7%	42,805	14.0%	16,440	5.4%	229,534	75.1%	6,378	2.1%	305,511	100.0%

Number of Protocols : 320

Comments:

Substantial numbers of women and minorities were enrolled in Phase III research protocols funded in 1997. There were more females (228,417 or 74.8%) than males (74,389 or 24.3%) enrolled in Phase III research protocols. Among minority subjects, the largest racial minority group is Black, non-Hispanic at 42,805 or 14.0%. Smallest identified racial group is American Indian/Alaska Natives at 5,030 or 1.6%.

**Aggregate Enrollment Data for Extramural Phase III Protocols
Funded in FY1997**

Table 97E. Distribution of Participants (Numbers)

	American Indians and Alaska Natives	Asian and Pacific Islander	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	2,902	4,490	26,402	10,013	181,603	3,007	228,417
Male	2,127	834	16,256	6,423	47,829	920	74,389
Unknown	1	0	147	4	102	2,451	2,705
Total	5,030	5,324	42,805	16,440	229,534	6,378	305,511

Table 97F. Distribution of Participants (Percentage)

	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	1.3%	2.0%	11.6%	4.4%	79.5%	1.3%	74.8%
Male	2.9%	1.1%	21.9%	8.6%	64.3%	1.2%	24.3%
Unknown	0.0%	0.0%	5.4%	0.1%	3.8%	90.6%	0.9%
Total	1.6%	1.7%	14.0%	5.4%	75.1%	2.1%	100.0%

**Table 97G. Aggregate Enrollment Data for Intramural Research Protocols
Conducted at the Warren G. Magnuson Clinical Center
Funded in FY1997**

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	8	0.1%	309	4.3%	887	12.4%	257	3.6%	5,578	78.2%	97	1.4%	7,136	49.6%
Male	13	0.2%	308	4.2%	699	9.6%	207	2.9%	5,954	82.1%	73	1.0%	7,254	50.4%
Unknown	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total	21	0.1%	617	4.3%	1,586	11.0%	464	3.2%	11,532	80.1%	170	1.2%	14,390	100.0%

Number of Protocols: 642

Comments:

Women and men have about equal participation in aggregate Intramural Research protocols.
Largest identified racial group is White, Not-Hispanic at 11,532 or 80.1%.
Largest identified racial minority group is Black, Not-Hispanic at 1,586 or 11.0%.
Smallest identified racial minority group is American Indian/Alaska Native at 21 or 0.1%.
Clinical Center is engaged in outreach to minority groups to encourage participation.

**Aggregate Enrollment Data for Intramural Research Protocols Conducted
at the Warren G. Magnuson Clinical Center
Funded in FY1997**

Table 97H. Distribution of Participants (Number)

	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	8	309	887	257	5,578	97	7,136
Male	13	308	699	207	5,954	73	7,254
Unknown	0	0	0	0	0	0	0
Total	21	617	1,586	464	11,532	170	14,390

Table 97I. Distribution of Participants (Percentage)

	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	0.1%	4.3%	12.4%	3.6%	78.2%	1.4%	49.6%
Male	0.2%	4.2%	9.6%	2.9%	82.1%	1.0%	50.4%
Unknown	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	0.1%	4.3%	11.0%	3.2%	80.1%	1.2%	100.0%

**Table 97J. Aggregate Enrollment Data for Intramural Research Protocols
Conducted Off-Site in FY 1997**

	American Indians and Alaska Natives		Asian and Pacific Islanders		Black - Not Hispanic		Hispanic		White - Not Hispanic		Other and Unknown		Total	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Female	1,579	0.33%	186,222	38.82%	29,354	6.12%	5,737	1.20%	248,139	51.73%	8,637	1.80%	479,668	48.64%
Male	1,508	0.33%	178,514	39.50%	15,343	3.39%	6,527	1.44%	239,614	53.01%	10,481	2.32%	451,987	45.84%
Unknown	11,843	21.76%	814	1.50%	14,628	26.87%	1,431	2.63%	481	0.88%	25,235	46.36%	54,432	5.52%
Total	14,930	1.51%	365,550	37.07%	59,325	6.02%	13,695	1.39%	488,234	49.51%	44,353	4.50%	986,087	100.00%

Total Number of Protocols: 161

Comments:

More females (479,668 or 48.6%) than males (451,987 or 45.8%) in aggregate Intramural Research Protocols
Among the minority groups, the largest identified racial group is Asian/Pacific Islander at 365,550 or 37.1%.
More males (10,481 or 2.32%) than females (8,637 or 1.80%) have not identified a racial group.
Smallest identified racial group is Hispanic at 13,695 or 1.39%.

**Aggregate Enrollment Data for Intramural Research Protocols
Conducted Off-Site in FY1997**

Table 97K. Distribution of Participants (Number)

	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	1,579	186,222	29,354	5,737	248,139	8,637	479,668
Male	1,508	178,514	15,343	6,527	239,614	10,481	451,987
Unknown	11,843	814	14,628	1,431	481	25,235	54,432
Total	14,930	365,550	59,325	13,695	488,234	44,353	986,087

Table 97L. Distribution of Participants (Percentage)

	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	0.33%	38.82%	6.12%	1.20%	51.73%	1.80%	48.64%
Male	0.33%	39.50%	3.39%	1.44%	53.01%	2.32%	45.84%
Unknown	21.76%	1.50%	26.87%	2.63%	0.88%	46.36%	5.52%
Total	1.51%	37.07%	6.02%	1.39%	49.51%	4.50%	100.00%

Additional General Accounting Office (GAO) Report Tables

GAO Report Table 1

Aggregate Enrollment for NIH Extramural and Intramural Research FY1997 (By Percentage)				
Gender	Extramural		Intramural	
	All	Phase III Only	On-site	Off-Site
Female	61.9%	74.8%	49.6%	50.0%
Male	37.1%	24.3%	50.4%	39.9%
Unknown	1.0%	0.9%	0.0%	10.1%

GAO Report Table 2

Aggregate Enrollment for NIH Extramural Research Excluding Male-Only & Female-only Protocols FY 1997 (By Percentage)							
	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
Female	1.6%	9.6%	20.8%	10.5%	51.6%	5.9%	52.1%
Male	1.3%	12.5%	17.2%	8.9%	53.7%	6.4%	46.6%
Unknown	0.7%	1.9%	5.8%	6.5%	33.0%	52.2%	1.3%

GAO Report Table 3

Aggregate Enrollment of FEMALE MINORITIES in NIH Extramural and Intramural Research FY 1997 (By Percentage)							
	American Indians and Alaska Natives	Asian and Pacific Islanders	Black - Not Hispanic	Hispanic	White - Not Hispanic	Other and Unknown	Total
All Extramural	1.1%	15.4%	17.2%	7.7%	52.7%	5.9%	61.9%
Phase III Extramural	1.3%	2.0%	11.6%	4.4%	79.5%	1.3%	74.8%
On-Site Intramural	0.1%	4.3%	12.4%	3.6%	78.2%	1.4%	49.6%
Off-Site Intramural	0.2%	55.3%	3.8%	0.5%	38.4%	1.8%	50.0%

* Based on special request from the May 2000 GAO Report.

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. 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

IC	Members
NCI	Diane Bronzert, Jane Cassidy, Otis Brawley, Marilyn Gaston, Karen Bashir, George Alexander, Marvin Kalt
NCRR	Dolores Lee, Barbara Perrone, Louise Ramm, Jan Heffernan, Geoff Cheung
NEI	Jack McLaughlin, Lore Ann McNicol
NHGRI	Monique Mansoura
NHLBI	Carl Roth, Sharry Palagi, Barbara Liu, Ralph Van Wey, Bill Wagner, Janita Coen
NIA	Miriam Kelty, David Reiter
NIAAA	Anne Phillips, Carmen Richardson, Nancy Brennan
NIAID	Joan Kondratick, Diane Yerg, Lai Tan, Milton Hernandez, Susan Marshall
NIAMS	Joanne Odenkirchen, Julia Freeman
NICHHD	Darlene Levenson, Douglas Shawver, Yvonne Maddox
NIDA	Jack Manischewitz, Mark Sweiter
NIDCD	Julie Gulya, Lynnette Hemsley, Beth Ansel, Susa Hamilton
NIDDK	Walter Stolz, Beth Paterson
NIDCR	Norman Braveman, Patricia Bryant
NIEHS	Martha Barnes
NIGMS	Alison Cole, Marcia Hahn
NIMH	Mary Blehar, Sherman Ragland, Charles Havekost
NINDS	Mary Graham, Constance Atwell, Mary Ellen Cheung, Mark Hallet
NINR	Carole Hudgings, Robin Gruber
NLM	Dwight Mowery, John Seachrist
FIC	Kathleen Michels
CC	Jerry King, Kai Lakeman
OIR	Alan Sandler, Deloris Mills
ORWH	Vivian Pinn, Virginia Hartmuller, Angela Bates