

Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review for the Fiscal Period 2001-2003

Council Dates		Jan-02	May-02	Aug-02	Oct-02	Jan-03	May-03	Aug-03	Oct-03
Total Number of Applications Reviewed	(#)	14,372	16,020	1,370	16,868	16,227	19,572	2,444	21,754
Number of Applications with Human Subjects	(#)	5,836	6,892	733	7,005	6,550	8,340	554	8,786
Number (percent) of Applications approved by IRG as submitted	(#)	5,447	6,438	683	6,572	6,229	7,875	526	8,333
	(%)	93.33%	93.41%	93.18%	93.82%	95.10%	94.42%	94.95%	94.84%
Number (percent) of Applications with unacceptable <i>minority-only</i> inclusion	(#)	168	167	21	171	127	170	5	152
	(%)	2.88%	2.42%	2.86%	2.44%	1.94%	2.04%	0.90%	1.73%
Number (percent) of Applications with unacceptable <i>sex/gender-only</i> inclusion	(#)	31	30	1	34	30	42	6	51
	(%)	0.53%	0.44%	0.14%	0.49%	0.46%	0.50%	1.08%	0.58%
Number (percent) of Applications with both unacceptable <i>minority</i> AND <i>sex/gender</i> inclusion	(#)	190	257	28	228	164	253	17	250
	(%)	3.26%	3.73%	3.82%	3.25%	2.50%	3.03%	3.07%	2.85%
Total Number (percent) of Applications with unacceptable <i>minority</i> inclusion	(#)	358	424	49	399	291	423	22	402
	(%)	6.13%	6.15%	6.68%	5.70%	4.44%	5.07%	3.97%	4.58%
Total Number (percent) of Applications with unacceptable <i>sex/gender</i> inclusion	(#)	221	287	29	262	194	295	23	301
	(%)	3.79%	4.16%	3.96%	3.74%	2.96%	3.54%	4.15%	3.43%
Total Number (percent) of unacceptable Applications as submitted	(#)	389	454	50	433	321	465	28	453
	(%)	6.67%	6.59%	6.82%	6.18%	4.90%	5.58%	5.05%	5.16%

Table B. Extramural Research Awards Funded for the Fiscal Period 2002-2003: Bars-To-Funding and Resolutions

Council Dates		Jan-02	May-02	Aug-02	Oct-02	Jan-03	May-03	Aug-03	Oct-03
Total number of awards	(#)	4,517	5,103	399	4,613	4,850	5,687	258	4,013
Number of awards involving Human Subjects	(#)	1,704	2,041	220	1,718	1,822	2,256	149	1,432
Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted	(#)	1,653	1,964	207	1,672	1,778	2,199	133	1,393
	(%)	97.01%	96.23%	94.09%	97.32%	97.59%	97.47%	89.26%	97.28%
Number (percent) of awards where <i>minority-only</i> bar-to-funding was removed by program staff (M_U)	(#)	19	32	3	20	14	24	11	9
	(%)	1.12%	1.57%	1.36%	1.16%	0.77%	1.06%	7.38%	0.63%
Number (percent) of awards where <i>sex/gender-only</i> bar-to-funding was removed by program staff (G_U)	(#)	5	6	0	7	7	9	2	3
	(%)	0.29%	0.29%	0.00%	0.41%	0.38%	0.40%	1.34%	0.21%
Number (percent) of awards where both <i>minority</i> AND <i>sex/gender</i> bar-to-funding were removed by program staff	(#)	27	39	10	19	23	24	3	27
	(%)	1.58%	1.91%	4.55%	1.11%	1.26%	1.06%	2.01%	1.89%
Total Number (percent) of awards where <i>minority</i> bar-to-funding was removed by program staff	(#)	46	71	13	39	37	48	14	36
	(%)	2.70%	3.48%	5.91%	2.27%	2.03%	2.13%	9.40%	2.51%
Total Number (percent) of awards where <i>sex/gender</i> bar-to-funding was removed by program staff	(#)	32	45	10	26	30	33	5	30
	(%)	1.88%	2.20%	4.55%	1.51%	1.65%	1.46%	3.36%	2.09%
Total Number (percent) of awards where bar-to-funding was removed	(#)	51	77	13	46	44	57	16	39
	(%)	2.99%	3.77%	5.91%	2.68%	2.41%	2.53%	10.74%	2.72%

Table C. Inclusion by Sex in All Research Studies Active and Funded in FY2002 and Reported in FY2003

	Extramural Studies		Intramural Studies	
	Phase III trials*	Other Clinical trials**	On-Site	Off-Site
Protocols reporting women only	186	1131	84	40
Protocols reporting men only	81	441	78	17
Protocols reporting both men and women	528	6037	904	190
Protocols reporting men, women, and unknown	35	379	5	28
Protocols reporting sex composition as unknown only	1	55	0	6
Protocols reporting men and unknown	0	2	0	1
Protocols reports women and unknown	2	8	0	2
Early Stage studies where enrollment data has not yet been submitted	122	3869	0	0
Totals	955	11922	1071	284

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

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

*** Many studies may be generic.

**Table C-1. Examples of Single Sex Extramural Research Studies
Funded in FY 2002 and Reported in FY 2003**

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

Osteoporotic Fractures in Men (MR OS)
High dose Chemotherapy and combination anti-HIV Therapy
Physicians Health Study II: Prevention Trial of Vitamins
Parenting psychotherapy for drug-dependent fathers
HIV Risk and Club Drugs among MSM
Evaluation and Treatment of Pain
Gene Environment Cancer Prevention
Mechanisms Linking Depression To Cardiovascular Risk
Gene Expression in Normal & Diseased Muscle Development
The Biological Basis of Alcohol-Induced Brain Damage
Osteoporotic Fractures in Men
Molecular Epidemiology of Testicular Carcinoma
Genetic Predisposition to Noise Induced Hearing Loss
Spit Tobacco (ST) Cessation: Rural High School Males

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

Brief Intervention to Prevent Prenatal Alcohol Use
Risk factors for Physical Disability in Aging Women
A Clinical Trial to Determine the Worth of Tamoxifen
Low Fat Diet and Breast Cancer Recurrence - Outcome Trial
Prevention of HIV and STDs in Drug-Using Women
Effects of Partner Violence Victimization in Drug-Use
Etanercept Therapy for Sjogren's Syndrome
Exercise Training in Obesity-Prone Black and White Women
Placental Glucose Transport in Diabetic Pregnancies
Risk Factors for Uterine Fibroids: A Case Control
Cognitive Behavioral Therapy for Vulvodynia
Pathogenesis of health Disparities in Preterm Birth
Risk Of Change In Women With Polycystic Ovary Syndrome
Chronic Life Stress And Incident Asthma In Adult Women
Psychobiology of Eating Behavior in Eating Disorders
Treatment of Women with Depression and Sexual Abuse
Raloxifene and Alendronate Comparison in Postmenopausal
Calcium and Vitamin D Malnutrition in Elderly Women
Women's Antioxidant Cardiovascular Study
HCV and Progression of HIV and HAART Response in
Parathyroid Hormone in Addition to Alendronate for
Carpel tunnel Syndrome Diagnosis and Treatment Trial
Methadone and Bupernorphine: Ante and Post-Partum
Gestational Diabetes: Diagnostic Criteria and Outcomes
Insulin and the Polycystic Ovary Syndrome
Decision Delay in Women with Acute Myocardial Infarction

Table 1: Aggregate Enrollment Data for All Extramural Research Protocols Funded in FY2002 and Reported in FY2003

Number of Protocols with Enrollment Data: **3,733**

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

	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	9,040	288,674	233,746		139,103	1,171,556		81,921	1,924,040
	0.28%	8.93%	7.23%	0.00%	4.30%	36.23%	0.00%	2.53%	59.49%
Male	7,183	244,143	138,232		84,976	746,750		56,812	1,278,096
	0.22%	7.55%	4.27%	0.00%	2.63%	23.09%	0.00%	1.76%	39.52%
Unknown	2,059	7,082	2,521		1,299	7,032		11,847	31,840
	0.06%	0.22%	0.08%	0.00%	0.04%	0.22%	0.00%	0.37%	0.98%
Total	18,282	539,899	374,499		225,378	1,925,338		150,580	3,233,976
	0.57%	16.69%	11.58%	0.00%	6.97%	59.53%	0.00%	4.66%	100.00%

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

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

Number of Protocols with Enrollment Data: **5,153**

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	42,491	759,689	610,265	15,952	3,503,273	55,890	744,551	5,732,111	4,646,305	381,137	704,669	5,732,111
	0.45%	8.10%	6.51%	0.17%	37.36%	0.60%	7.94%	61.12%	49.54%	4.06%	7.51%	61.12%
Male	18,087	1,084,087	339,345	14,523	1,850,378	43,192	207,811	3,557,423	3,148,264	226,429	182,730	3,557,423
	0.19%	11.56%	3.62%	0.15%	19.73%	0.46%	2.22%	37.93%	33.57%	2.41%	1.95%	37.93%
Unknown	1,383	1,713	7,829	5,772	14,936	448	56,525	88,606	20,872	2,251	65,483	88,606
	0.01%	0.02%	0.08%	0.06%	0.16%	0.00%	0.60%	0.94%	0.22%	0.02%	0.70%	0.94%
Total	61,961	1,845,489	957,439	36,247	5,368,587	99,530	1,008,887	9,378,140	7,815,441	609,817	952,882	9,378,140
	0.66%	19.68%	10.21%	0.39%	57.25%	1.06%	10.76%	100.00%	83.34%	6.50%	10.16%	100.00%

TOTAL	TOTAL	TOTAL	TOTAL	OVERALL
Females	7,656,151	Males	4,835,519	Total
	60.70%		38.34%	120,446
				0.96%
				12,612,116
				100%

Table 1: Aggregate Enrollment Data for All Extramural Research Protocols Funded in FY2002 and Reported in FY2003

Data Table Comments:

More females (7,656,151 or 60.7%) than males (4,835,519 or 38.34%) are enrolled in aggregate extramural research protocols.
Largest identified racial group is White at 59.53% following the 1977 OMB standards and 57.25% following the 1997 OMB standards.

Largest identified racial minority group is Asian at 16.69% following the 1977 OMB standards and 19.68% following the 1997 OMB standards.
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native at (0.6%).
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.4%).
6.5% of participants identified their ethnicity as Hispanic or Latino.

Table 1A: Percent Analysis for All Extramural Research Protocols Funded in FY2002 Reported in FY2003

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

	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	Hispanic	White	More Than One Race	Unknown/ Other	Total
Female	9,040	288,674	233,746		139,103	1,171,556		81,921	1,924,040
	0.28%	8.93%	7.23%		4.30%	36.23%		2.53%	59.49%
	<i>0.47%</i>	<i>15.00%</i>	<i>12.15%</i>		<i>7.23%</i>	<i>60.89%</i>		<i>4.26%</i>	<i>100.00%</i>
	49.45%	53.47%	62.42%		61.72%	60.85%		54.40%	59.49%
Male	7,183	244,143	138,232		84,976	746,750		56,812	1,278,096
	0.22%	7.55%	4.27%		2.63%	23.09%		1.76%	39.52%
	<i>0.56%</i>	<i>19.10%</i>	<i>10.82%</i>		<i>6.65%</i>	<i>58.43%</i>		<i>4.45%</i>	<i>100.00%</i>
	39.29%	45.22%	36.91%		37.70%	38.79%		37.73%	39.52%
Unknown	2,059	7,082	2,521		1,299	7,032		11,847	31,840
	0.06%	0.22%	0.08%		0.04%	0.22%		0.37%	0.98%
	<i>6.47%</i>	<i>22.24%</i>	<i>7.92%</i>		<i>4.08%</i>	<i>22.09%</i>		<i>37.21%</i>	<i>100.00%</i>
	11.26%	1.31%	0.67%		0.58%	0.37%		7.87%	0.98%
Total	18,282	539,899	374,499		225,378	1,925,338		150,580	3,233,976
	0.57%	16.69%	11.58%		6.97%	59.53%		4.66%	100.00%
	<i>0.57%</i>	<i>16.69%</i>	<i>11.58%</i>		<i>6.97%</i>	<i>59.53%</i>		<i>4.66%</i>	<i>100.00%</i>
	100.00%	100.00%	100.00%		100.00%	100.00%		100.00%	100.00%

Legend

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

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

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

Table 1A: Percent Analysis for All Extramural Research Protocols Funded in FY2002 Reported in FY2003

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

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	42,491	759,689	610,265	15,952	3,503,273	55,890	744,551	5,732,111	4,646,305	381,137	704,669	5,732,111
	0.45%	8.10%	6.51%	0.17%	37.36%	0.60%	7.94%	61.12%	49.54%	4.06%	7.51%	61.12%
	<i>0.74%</i>	<i>13.25%</i>	<i>10.65%</i>	<i>0.28%</i>	<i>61.12%</i>	<i>0.98%</i>	<i>12.99%</i>	<i>100.00%</i>	<i>81.06%</i>	<i>6.65%</i>	<i>12.29%</i>	<i>100.00%</i>
	68.58%	41.16%	63.74%	44.01%	65.26%	56.15%	73.80%	61.12%	59.45%	62.50%	73.95%	61.12%
Male	18,087	1,084,087	339,345	14,523	1,850,378	43,192	207,811	3,557,423	3,148,264	226,429	182,730	3,557,423
	0.19%	11.56%	3.62%	0.15%	19.73%	0.46%	2.22%	37.93%	33.57%	2.41%	1.95%	37.93%
	<i>0.51%</i>	<i>30.47%</i>	<i>9.54%</i>	<i>0.41%</i>	<i>52.01%</i>	<i>1.21%</i>	<i>5.84%</i>	<i>100.00%</i>	<i>88.50%</i>	<i>6.36%</i>	<i>5.14%</i>	<i>100.00%</i>
	29.19%	58.74%	35.44%	40.07%	34.47%	43.40%	20.60%	37.93%	40.28%	37.13%	19.18%	37.93%
Unknown	1,383	1,713	7,829	5,772	14,936	448	56,525	88,606	20,872	2,251	65,483	88,606
	0.01%	0.02%	0.08%	0.06%	0.16%	0.00%	0.60%	0.94%	0.22%	0.02%	0.70%	0.94%
	<i>1.56%</i>	<i>1.93%</i>	<i>8.84%</i>	<i>6.51%</i>	<i>16.86%</i>	<i>0.51%</i>	<i>63.79%</i>	<i>100.00%</i>	<i>23.56%</i>	<i>2.54%</i>	<i>73.90%</i>	<i>100.00%</i>
	2.23%	0.09%	0.82%	15.92%	0.28%	0.45%	5.60%	0.94%	0.27%	0.37%	6.87%	0.94%
Total	61,961	1,845,489	957,439	36,247	5,368,587	99,530	1,008,887	9,378,140	7,815,441	609,817	952,882	9,378,140
	0.66%	19.68%	10.21%	0.39%	57.25%	1.06%	10.76%	100.00%	83.34%	6.50%	10.16%	100.00%
	<i>0.66%</i>	<i>19.68%</i>	<i>10.21%</i>	<i>0.39%</i>	<i>57.25%</i>	<i>1.06%</i>	<i>10.76%</i>	<i>100.00%</i>	<i>83.34%</i>	<i>6.50%</i>	<i>10.16%</i>	<i>100.00%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

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

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

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

Table 2. Aggregate Enrollment Data for All Extramural Research Protocols Funded in FY 2001 and Reported in FY 2002

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards										Number of Protocols with Enrollment Data: 4,935	
	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/Other	Total		
Female	16,559	405,345	354,133		205,747	1,797,249		149,706	2,928,739		
	0.57%	13.84%	12.09%		7.03%	61.37%		5.11%	61.60%		
Male	11,611	349,340	234,725		143,848	984,407		76,193	1,800,124		
	0.65%	19.41%	13.04%		7.99%	54.69%		4.23%	37.86%		
Unknown	53	509	971		1,119	7,357		15,846	25,855		
	0.20%	1.97%	3.76%		4.33%	28.45%		61.29%	0.54%		
Total	28,223	755,194	589,829		350,714	2,789,013		241,745	4,754,718		
	0.59%	15.88%	12.41%		7.38%	58.66%		5.08%	100.00%		

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards										Number of Protocols with Enrollment Data: 2,758			
	Total of All Subjects by Race								Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total	
Female	51,173	271,731	371,468	8,554	1,946,559	18,376	641,925	3,309,786	2,237,035	208,844	863,907	3,309,786	
	1.55%	8.21%	11.22%	0.26%	58.81%	0.56%	19.39%	75.15%	67.59%	6.31%	26.10%	75.15%	
Male	26,272	79,857	168,857	7,981	698,010	12,267	62,019	1,055,263	813,756	81,853	159,654	1,055,263	
	2.49%	7.57%	16.00%	0.76%	66.15%	1.16%	5.88%	23.96%	77.11%	7.76%	15.13%	23.96%	
Unknown	289	2,461	7,451	5,101	6,972	312	16,418	39,004	21,161	1,732	16,111	39,004	
	0.74%	6.31%	19.10%	13.08%	17.88%	0.80%	42.09%	0.89%	54.25%	4.44%	41.31%	0.89%	
Total	77,734	354,049	547,776	21,636	2,651,541	30,955	720,362	4,404,053	3,071,952	292,429	1,039,672	4,404,053	
	1.77%	8.04%	12.44%	0.49%	60.21%	0.70%	16.36%	100.00%	69.75%	6.64%	23.61%	100.00%	

TOTAL		TOTAL		TOTAL		OVERALL	
Females	6,238,525	Males	2,855,387	Unknown	64,859	Total	9,158,771
	68.12%		31.18%		0.71%		100%

Table 2. Aggregate Enrollment Data for All Extramural Research Protocols Funded in FY 2001 and Reported in FY 2002

Data Table Comments:

More females (6,238,525 or 68.12%) than males (2,855,387 or 31.18%) are enrolled in aggregate extramural research protocols.
Largest identified racial group is White at 58.66% following the 1977 OMB standards and 60.21% following the 1997 OMB standards.
According to the 1977 OMB standards, the largest identified racial minority group is Asians (15.88%).
According to the 1997 OMB standards, the largest identified racial minority group is Blacks at (12.44%).
According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native at (0.6%).
According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.5%).
7% of participants identified their ethnicity as Hispanic or Latino.

**Table 3: Aggregate Enrollment Data for Extramural Research Protocols
Excluding Male-Only and Female-Only Protocols Funded in FY2002 and Reported in FY2003**

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards										Number of Protocols with Enrollment Data:	2,928
	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/O ther	Total		
Female	7,600	252,055	155,225		88,670	657,232		70,746	1,231,528		
	0.32%	10.61%	6.54%		3.73%	27.67%		2.98%	51.85%		
Male	6,945	238,520	127,005		81,248	622,193		35,696	1,111,607		
	0.29%	10.04%	5.35%		3.42%	26.20%		1.50%	46.80%		
Unknown	2,059	7,082	2,521		1,299	7,032		11,847	31,840		
	0.09%	0.30%	0.11%		0.05%	0.30%		0.50%	1.34%		
Total	16,604	497,657	284,751		171,217	1,286,457		118,289	2,374,975		
	0.70%	20.95%	11.99%		7.21%	54.17%		4.98%	100.00%		

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards										Number of Protocols with Enrollment Data:	4,119	
	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	19,433	702,652	398,067	14,420	2,135,257	45,357	247,379	3,562,565	3,099,235	242,698	220,632	3,562,565
	0.27%	9.91%	5.62%	0.20%	30.12%	0.64%	3.49%	50.26%	43.72%	3.42%	3.11%	50.26%
Male	17,802	1,049,877	326,199	14,454	1,787,209	41,580	200,330	3,437,451	3,041,215	219,633	176,603	3,437,451
	0.25%	14.81%	4.60%	0.20%	25.21%	0.59%	2.83%	48.49%	42.90%	3.10%	2.49%	48.49%
Unknown	1,383	1,713	7,829	5,772	14,936	448	56,525	88,606	20,872	2,251	65,483	88,606
	0.02%	0.02%	0.11%	0.08%	0.21%	0.01%	0.80%	1.25%	0.29%	0.03%	0.92%	1.25%
Total	38,618	1,754,242	732,095	34,646	3,937,402	87,385	504,234	7,088,622	6,161,322	464,582	462,718	7,088,622
	0.54%	24.75%	10.33%	0.49%	55.55%	1.23%	7.11%	100.00%	86.92%	6.55%	6.53%	100.00%

TOTAL	TOTAL	TOTAL	TOTAL	OVERALL
Females	4,794,093	Males	4,549,058	Total
	50.66%		48.07%	9,463,597
				1.27%
				100%

**Table 3: Aggregate Enrollment Data for Extramural Research Protocols
Excluding Male-Only and Female-Only Protocols Funded in FY2002 and Reported in FY2003**

Data Table Comments:

There were 8,886 protocols of which 1,317 were *female-only* protocols and 522 were *male-only* protocols.

Excluding sex-specific studies, the number of females (4,794,093 or 50.6%) to males (4,549,058 or 48.1%) enrolled in extramural research protocols

Largest identified racial group is White at 54.2% following the 1977 OMB standards and 55.5% following the 1997 OMB standards.

Largest identified racial minority group is Asian at 20.95% following the 1977 OMB standards and 24.8% following the 1997 OMB standards.

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

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.497%).

6.55 of participants identified their ethnicity as Hispanic or Latino.

Table 4. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY 2001 and Reported in FY 2002

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards									Number of Protocols with Enrollment Data:	3,938
	American Indian/Alaska Native	Asian	Black	* Hawaiian/Pacific Islander	Hispanic	White	*More Than One Race	Unknown/Other	Total	
Female	12,476	361,471	258,829		144,161	850,748		78,036	1,705,721	
	0.73%	21.19%	15.17%		8.45%	49.88%		4.57%	49.48%	
Male	11,269	345,810	226,443		139,031	919,272		73,583	1,715,408	
	0.66%	20.16%	13.20%		8.10%	53.59%		4.29%	49.77%	
Unknown	53	509	971		1,119	7,357		15,846	25,855	
	0.20%	1.97%	3.76%		4.33%	28.45%		61.29%	0.75%	
Total	23,798	707,790	486,243		284,311	1,777,377		167,465	3,446,984	
	0.69%	20.53%	14.11%		8.25%	51.56%		4.86%	100.00%	

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data:	2,266		
	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/Alaska Native	Asian	Black	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	Not Hispanic	Hispanic or Latino	Unknown/Not Reported	Total
Female	27,471	73,888	199,564	8,231	745,791	12,665	86,501	1,154,111	805,206	86,756	262,149	1,154,111
	2.38%	6.40%	17.29%	0.71%	64.62%	1.10%	7.50%	52.47%	69.77%	7.52%	22.71%	52.47%
Male	26,096	75,650	162,359	7,958	664,642	11,541	58,129	1,006,375	774,209	79,388	152,778	1,006,375
	2.59%	7.52%	16.13%	0.79%	66.04%	1.15%	5.78%	45.75%	76.93%	7.89%	15.18%	45.75%
Unknown	289	2,461	7,451	5,101	6,972	312	16,418	39,004	21,161	1,732	16,111	39,004
	0.74%	6.31%	19.10%	13.08%	17.88%	0.80%	42.09%	1.77%	54.25%	4.44%	41.31%	1.77%
Total	53,856	151,999	369,374	21,290	1,417,405	24,518	161,048	2,199,490	1,600,576	167,876	431,038	2,199,490
	2.45%	6.91%	16.79%	0.97%	64.44%	1.11%	7.32%	100.00%	72.77%	7.63%	19.60%	100.00%

TOTAL	TOTAL	TOTAL	TOTAL	OVERALL
Females	2,859,832	Males	2,721,783	Total
	50.65%		48.20%	5,646,474
			1.15%	100%

Table 4. Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols Funded in FY 2001 and Reported in FY 2002

Data Table Comments:

There were 7,693 protocols of which 1,049 were *female-only* protocols and 440 were *male-only* protocols.

Excluding sex-specific studies, the number of females (2,859,832 or 50.65%) to males (2,721,783 or 48.20%) enrolled in extramural research protocols are closely representative of the general population.

Largest identified racial group is White at 51.5% following the 1977 OMB standards and 64.4% following the 1997 OMB standards.

According to the 1977 OMB standards, the largest identified racial minority group is Asian (20.53%).

According to the 1997 OMB standards, the largest identified racial minority group is Blacks at (16.8%).

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

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.97%).

7.63% of participants identified their ethnicity as Hispanic or Latino.

**Table 5: Aggregate Enrollment Data for Extramural Phase III Research Protocols
Funded in FY2002 and Reported in FY2003**

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

Number of Protocols
with Enrollment Data: 628

	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	1,040	4,843	30,110		16,236	193,734		4,580	250,543
	0.24%	1.11%	6.92%		3.73%	44.51%		1.05%	57.57%
Male	648	3,152	20,571		12,680	142,250		4,355	183,656
	0.15%	0.72%	4.73%		2.91%	32.68%		1.00%	42.20%
Unknown	0	0	1		84	20		918	1,023
	0.00%	0.00%	0.00%		0.02%	0.00%		0.21%	0.24%
Total	1,688	7,995	50,682		29,000	336,004		9,853	435,222
	0.39%	1.84%	11.65%		6.66%	77.20%		2.26%	100.00%

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

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

Number of Protocols
with Enrollment Data: 205

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	160	1,708	12,752	75	18,090	765	2,680	36,230	27,495	3,022	5,713	36,230
	0.20%	2.18%	16.31%	0.10%	23.13%	0.98%	3.43%	46.33%	35.16%	3.86%	7.31%	46.33%
Male	238	1,414	9,316	78	25,231	437	4,290	41,004	32,586	4,795	3,623	41,004
	0.30%	1.81%	11.91%	0.10%	32.26%	0.56%	5.49%	52.43%	41.67%	6.13%	4.63%	52.43%
Unknown	0	2	10	0	46	1	910	969	55	4	910	969
	0.00%	0.00%	0.01%	0.00%	0.06%	0.00%	1.16%	1.24%	0.07%	0.01%	1.16%	1.24%
Total	398	3,124	22,078	153	43,367	1,203	7,880	78,203	60,136	7,821	10,246	78,203
	0.51%	3.99%	28.23%	0.20%	55.45%	1.54%	10.08%	100.00%	76.90%	10.00%	13.10%	100.00%

TOTAL		TOTAL		TOTAL		OVERALL	
Females	286,773	Males	224,660	Unknown	1,992	Total	513,425
	55.85%		43.76%		0.39%		100%

**Table 5: Aggregate Enrollment Data for Extramural Phase III Research Protocols
Funded in FY2002 and Reported in FY2003**

Data Table Comments:

Substantial numbers of women and minorities are enrolled in Phase III research protocols funded in FY2002 and reported in FY2003. More females (286,733 or 55.8%) than males (224,660 or 43.7%) are enrolled in aggregate extramural research protocols. Largest identified racial group is White at 77.2% following the 1977 OMB standards and 55.5% following the 1997 OMB standards.

Largest identified racial minority group is Black at 11.6% following the 1977 OMB standards and 28.2% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native at (0.4%). According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.20%). 10% of participants identified their ethnicity as Hispanic or Latino.

Table 5A: Percent Analysis of Phase III Research Protocols Funded in FY2002 and Reported in FY2003

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

	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	Hispanic	White	More Than One Race	Unknown/ Other	Total
Female	1,040	4,843	30,110		16,236	193,734		4,580	250,543
	0.24%	1.11%	6.92%		3.73%	44.51%		1.05%	57.57%
	<i>0.42%</i>	<i>1.93%</i>	<i>12.02%</i>		<i>6.48%</i>	<i>77.33%</i>		<i>1.83%</i>	<i>100.00%</i>
	61.61%	60.58%	59.41%		55.99%	57.66%		46.48%	57.57%
Male	648	3,152	20,571		12,680	142,250		4,355	183,656
	0.15%	0.72%	4.73%		2.91%	32.68%		1.00%	42.20%
	<i>0.35%</i>	<i>1.72%</i>	<i>11.20%</i>		<i>6.90%</i>	<i>77.45%</i>		<i>2.37%</i>	<i>100.00%</i>
	38.39%	39.42%	40.59%		43.72%	42.34%		44.20%	42.20%
Unknown	0	0	1		84	20		918	1,023
	0.00%	0.00%	0.00%		0.02%	0.00%		0.21%	0.24%
	<i>0.00%</i>	<i>0.00%</i>	<i>0.10%</i>		<i>8.21%</i>	<i>1.96%</i>		<i>89.74%</i>	<i>100.00%</i>
	0.00%	0.00%	0.00%		0.29%	0.01%		9.32%	0.24%
Total	1,688	7,995	50,682		29,000	336,004		9,853	435,222
	0.39%	1.84%	11.65%		6.66%	77.20%		2.26%	100.00%
	<i>0.39%</i>	<i>1.84%</i>	<i>11.65%</i>		<i>6.66%</i>	<i>77.20%</i>		<i>2.26%</i>	<i>100.00%</i>
	100.00%	100.00%	100.00%		100.00%	100.00%		100.00%	100.00%

Legend

Bold: % of Total No. of Participants in Research Protocols (Old or New form)

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

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

Table 5A: Percent Analysis of Phase III Research Protocols Funded in FY2002 and Reported in FY2003

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

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	160	1,708	12,752	75	18,090	765	2,680	36,230	27,495	3,022	5,713	36,230
	0.20%	2.18%	16.31%	0.10%	23.13%	0.98%	3.43%	46.33%	35.16%	3.86%	7.31%	46.33%
	<i>0.44%</i>	<i>4.71%</i>	<i>35.20%</i>	<i>0.21%</i>	<i>49.93%</i>	<i>2.11%</i>	<i>7.40%</i>	<i>100.00%</i>	<i>75.89%</i>	<i>8.34%</i>	<i>15.77%</i>	<i>100.00%</i>
	40.20%	54.67%	57.76%	49.02%	41.71%	63.59%	34.01%	46.33%	45.72%	38.64%	55.76%	46.33%
Male	238	1,414	9,316	78	25,231	437	4,290	41,004	32,586	4,795	3,623	41,004
	0.30%	1.81%	11.91%	0.10%	32.26%	0.56%	5.49%	52.43%	41.67%	6.13%	4.63%	52.43%
	<i>0.58%</i>	<i>3.45%</i>	<i>22.72%</i>	<i>0.19%</i>	<i>61.53%</i>	<i>1.07%</i>	<i>10.46%</i>	<i>100.00%</i>	<i>79.47%</i>	<i>11.69%</i>	<i>8.84%</i>	<i>100.00%</i>
	59.80%	45.26%	42.20%	50.98%	58.18%	36.33%	54.44%	52.43%	54.19%	61.31%	35.36%	52.43%
Unknown	0	2	10	0	46	1	910	969	55	4	910	969
	0.00%	0.00%	0.01%	0.00%	0.06%	0.00%	1.16%	1.24%	0.07%	0.01%	1.16%	1.24%
	<i>0.00%</i>	<i>0.21%</i>	<i>1.03%</i>	<i>0.00%</i>	<i>4.75%</i>	<i>0.10%</i>	<i>93.91%</i>	<i>100.00%</i>	<i>5.68%</i>	<i>0.41%</i>	<i>93.91%</i>	<i>100.00%</i>
	0.00%	0.06%	0.05%	0.00%	0.11%	0.08%	11.55%	1.24%	0.09%	0.05%	8.88%	1.24%
Total	398	3,124	22,078	153	43,367	1,203	7,880	78,203	60,136	7,821	10,246	78,203
	0.51%	3.99%	28.23%	0.20%	55.45%	1.54%	10.08%	100.00%	76.90%	10.00%	13.10%	100.00%
	<i>0.51%</i>	<i>3.99%</i>	<i>28.23%</i>	<i>0.20%</i>	<i>55.45%</i>	<i>1.54%</i>	<i>10.08%</i>	<i>100.00%</i>	<i>76.90%</i>	<i>10.00%</i>	<i>13.10%</i>	<i>100.00%</i>
	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Legend

Bold: % of Total No. of Participants in Research Protocols (Old or New form)

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

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

Table 6. Aggregate Enrollment Data for Extramural Phase III Research Protocols Funded in FY 2001 and Reported in FY 2002

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

Number of Protocols with Enrollment Data: 670

	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	Hispanic	White	More Than One Race	Unknown/ Other	Total
Female	1,307	24,958	55,358		44,705	229,803		7,658	363,789
	0.36%	6.86%	15.22%		12.29%	63.17%		2.11%	67.14%
Male	619	6,603	24,674		14,466	125,634		5,338	177,334
	0.35%	3.72%	13.91%		8.16%	70.85%		3.01%	32.73%
Unknown	0	2	33		8	95		547	685
	0.00%	0.29%	4.82%		1.17%	13.87%		79.85%	0.13%
Total	1,926	31,563	80,065		59,179	355,532		13,543	541,808
	0.36%	5.83%	14.78%		10.92%	65.62%		2.50%	100.00%

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

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

Number of Protocols with Enrollment Data: 87

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/Not Reported	Total
Female	81	385	2,834	4	15,027	274	859	19,464	17,697	781	986	19,464
	0.42%	1.98%	14.56%	0.02%	77.20%	1.41%	4.41%	52.50%	90.92%	4.01%	5.07%	52.50%
Male	57	1,508	2,287	4	12,244	151	1,099	17,350	15,695	560	1,095	17,350
	0.33%	8.69%	13.18%	0.02%	70.57%	0.87%	6.33%	46.80%	90.46%	3.23%	6.31%	46.80%
Unknown	0	1	2	0	14	1	241	259	140	31	88	259
	0.00%	0.39%	0.77%	0.00%	5.41%	0.39%	93.05%	0.70%	54.05%	11.97%	33.98%	0.70%
Total	138	1,894	5,123	8	27,285	426	2,199	37,073	33,532	1,372	2,169	37,073
	0.37%	5.11%	13.82%	0.02%	73.60%	1.15%	5.93%	100.00%	90.45%	3.70%	5.85%	100.00%

TOTAL		TOTAL		TOTAL		OVERALL	
Females	383,253	Males	194,684	Unknown	944	Total	578,881
	66.21%		33.63%		0.16%		100%

**Table 6. Aggregate Enrollment Data for Extramural Phase III Research Protocols
Funded in FY 2001 and Reported in FY 2002**

Data Table Comments:

Substantial numbers of women and minorities are enrolled in Phase III research protocols funded in FY2001 and reported in FY2002. More females (383,253 or 66.2%) than males (194,684 or 33.6%) are enrolled in aggregate extramural research protocols. Largest identified racial group is White at 65.6% following the 1977 OMB standards and 73.6% following the 1997 OMB standards. Largest identified racial minority group is Black at 14.8% following the 1977 OMB standards and 13.8% following the 1997 OMB standards. According to the 1977 OMB standards, the smallest identified racial minority group is American Indian/Alaskan Native at (0.3%). According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.02%). 3.7% of participants identified their ethnicity as Hispanic or Latino.

**Table 7: Aggregate Enrollment Data for Extramural Phase III Protocols
Excluding Male-Only and Female-Only Protocols Funded in FY2002 and Reported in FY2003**

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards									Number of Protocols with Enrollment Data:	413
	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total	
Female	476	1,485	15,439		10,543	61,405		2,074	91,422	
	0.23%	0.71%	7.35%		5.02%	29.25%		0.99%	43.55%	
Male	486	1,895	15,235		10,474	86,485		2,906	117,481	
	0.23%	0.90%	7.26%		4.99%	41.20%		1.38%	55.96%	
Unknown	0	0	1		84	20		918	1,023	
	0.00%	0.00%	0.00%		0.04%	0.01%		0.44%	0.49%	
Total	962	3,380	30,675		21,101	147,910		5,898	209,926	
	0.46%	1.61%	14.61%		10.05%	70.46%		2.81%	100.00%	

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data:	153		
	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	92	1,585	8,744	61	14,093	503	2,294	27,372	19,308	2,460	5,604	27,372
	0.14%	2.49%	13.76%	0.10%	22.17%	0.79%	3.61%	43.06%	30.37%	3.87%	8.82%	43.06%
Male	190	1,239	8,694	78	21,023	297	3,707	35,228	27,624	3,995	3,609	35,228
	0.30%	1.95%	13.68%	0.12%	33.07%	0.47%	5.83%	55.42%	43.46%	6.28%	5.68%	55.42%
Unknown	0	2	10	0	46	1	910	969	55	4	910	969
	0.00%	0.00%	0.02%	0.00%	0.07%	0.00%	1.43%	1.52%	0.09%	0.01%	1.43%	1.52%
Total	282	2,826	17,448	139	35,162	801	6,911	63,569	46,987	6,459	10,123	63,569
	0.44%	4.45%	27.45%	0.22%	55.31%	1.26%	10.87%	100.00%	73.91%	10.16%	15.92%	100.00%

TOTAL		TOTAL		TOTAL		OVERALL	
Females	118,794	Males	152,709	Unknown	1,992	Total	273,495
	43.44%		55.84%		0.73%		100%

**Table 7: Aggregate Enrollment Data for Extramural Phase III Protocols
Excluding Male-Only and Female-Only Protocols Funded in FY2002 and Reported in FY2003**

Data Table Comments:

There were 833 protocols of which 186 were *female-only* protocols and 81 were *male-only* protocols.

Excluding sex-specific studies, the number of females (118,794 or 43.4%) to males (152,709 or 55.8%) enrolled in extramural research protocols are closely representative of the general population.

Largest identified racial group is White at 70.5% following the 1977 OMB standards and 55.3% following the 1997 OMB standards.

Largest identified racial minority group is Black at 14.6% following the 1977 OMB standards and 27.4% following the 1997 OMB standards.

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

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.22%).

10.16% of participants identified their ethnicity as Hispanic or Latino.

Table 8. Aggregate Enrollment Data for Extramural Phase III Protocols Excluding Male-Only and Female-Only Protocols Funded in FY 2001 and Reported in FY 2002

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards Number of Protocols with Enrollment Data: 447

	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	554	5,107	19,887		12,857	75,234		3,147	116,786
	0.47%	4.37%	17.03%		11.01%	64.42%		2.69%	44.57%
Male	580	5,693	21,856		13,621	98,692		4,105	144,547
	0.40%	3.94%	15.12%		9.42%	68.28%		2.84%	55.17%
Unknown	0	2	33		8	95		547	685
	0.00%	0.29%	4.82%		1.17%	13.87%		79.85%	0.26%
Total	1,134	10,802	41,776		26,486	174,021		7,799	262,018
	0.43%	4.12%	15.94%		10.11%	66.42%		2.98%	100.00%

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards Number of Protocols with Enrollment Data: 67

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	51	226	1,615	4	4,441	144	633	7,114	5,768	461	885	7,114
	0.72%	3.18%	22.70%	0.06%	62.43%	2.02%	8.90%	42.03%	81.08%	6.48%	12.44%	42.03%
Male	54	1,300	1,403	4	5,839	148	805	9,553	8,194	402	957	9,553
	0.57%	13.61%	14.69%	0.04%	61.12%	1.55%	8.43%	56.44%	85.77%	4.21%	10.02%	56.44%
Unknown	0	1	2	0	14	1	241	259	140	31	88	259
	0.00%	0.39%	0.77%	0.00%	5.41%	0.39%	93.05%	1.53%	54.05%	11.97%	33.98%	1.53%
Total	105	1,527	3,020	8	10,294	293	1,679	16,926	14,102	894	1,930	16,926
	0.62%	9.02%	17.84%	0.05%	60.82%	1.73%	9.92%	100.00%	83.32%	5.28%	11.40%	100.00%

TOTAL	TOTAL	TOTAL	OVERALL
Females	123,900	Males	154,100
	44.42%		55.24%
		Unknown	944
			0.34%
		Total	278,944
			100%

Table 8. Aggregate Enrollment Data for Extramural Phase III Protocols Excluding Male-Only and Female-Only Protocols Funded in FY 2001 and Reported in FY 2002

Data Table Comments:

There were 757 protocols of which 181 were *female-only* protocols and 62 were *male-only* protocols.

Excluding sex-specific studies, the number of females (123,900 or 44.4%) to males (154,100 or 55.2%) enrolled in extramural research protocols are closely representative of the general population.

Largest identified racial group is White at 66.4% following the 1977 OMB standards and 60.8% following the 1997 OMB standards.

Largest identified racial minority group is Black at 15.9% following the 1977 OMB standards and 17.8% following the 1997 OMB standards.

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

According to the 1997 OMB standards, the smallest identified racial minority group is Hawaiian/Pacific Islander at (0.05%).

5.3% of participants identified their ethnicity as Hispanic or Latino.

Table 9: Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2002 and Reported in FY2003

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards									Number of Protocols with Enrollment Data: 1,199
	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	9,511	128,639	52,418		227,889	393,786		57,453	869,696
	0.52%	7.03%	2.86%		12.45%	21.51%		3.14%	47.50%
Male	8,896	63,520	50,943		418,626	346,942		57,058	945,985
	0.49%	3.47%	2.78%		22.86%	18.95%		3.12%	51.67%
Unknown	0	41	10		200	870		14,165	15,286
	0.00%	0.00%	0.00%		0.01%	0.05%		0.77%	0.83%
Total	18,407	192,200	103,371		646,715	741,598		128,676	1,830,967
	1.01%	10.50%	5.65%		35.32%	40.50%		7.03%	100.00%

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards									Number of Protocols with Enrollment Data: 156			
	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	2	75	312	1	1,024	3	107	1,524	1,388	99	37	1,524
	0.06%	2.42%	10.07%	0.03%	33.06%	0.10%	3.45%	49.21%	44.82%	3.20%	1.19%	49.21%
Male	10	105	225	0	1,161	3	69	1,573	1,487	64	22	1,573
	0.32%	3.39%	7.27%	0.00%	37.49%	0.10%	2.23%	50.79%	48.01%	2.07%	0.71%	50.79%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	12	180	537	1	2,185	6	176	3,097	2,875	163	59	3,097
	0.39%	5.81%	17.34%	0.03%	70.55%	0.19%	5.68%	100.00%	92.83%	5.26%	1.91%	100.00%

TOTAL	TOTAL	TOTAL	OVERALL
Females	871,220	Males	947,558
	47.50%		51.66%
		Unknown	15,286
			0.83%
		Total	1,834,064
			100%

Table 9: Aggregate Enrollment Data for Intramural Research Protocols Funded in FY2002 and Reported in FY2003

Data Table Comments:

There were more males (947,558 or 51.6%) than females (871,220 or 47.5%) enrolled in aggregate intramural research protocols. Differences in the enrollment of males and females is attributed primarily to improvements in reporting procedures (e.g. ensuring sex/gender declaration and recording at enrollment).

According to the 1977 OMB standards, the largest identified racial minority group is Hispanics at (35.32%).

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

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

According to the 1997 OMB standards, the largest identified racial minority group is Blacks at (17.34%).

5.3% of participants identified their ethnicity as Hispanic or Latino.

Table 10. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY 2001 and Reported in FY 2002

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards										Number of Protocols with Enrollment Data: 1,252
	American Indian/ Alaska Native	Asian	Black	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total	
Female	9,127	272,304	55,114		27,293	518,632		34,554	917,024	
	1.00%	29.69%	6.01%		2.98%	56.56%		3.77%	46.32%	
Male	8,491	194,723	57,250		20,458	735,946		32,305	1,049,173	
	0.81%	18.56%	5.46%		1.95%	70.15%		3.08%	53.00%	
Unknown	2	75	41		192	461		12,745	13,516	
	0.01%	0.55%	0.30%		1.42%	3.41%		94.30%	0.68%	
Total	17,620	467,102	112,405		47,943	1,255,039		79,604	1,979,713	
	0.89%	23.59%	5.68%		2.42%	63.39%		4.02%	100.00%	

*Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standards.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards										Number of Protocols with Enrollment Data: 0		
	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Male	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Total	0	0	0	0	0	0	0	0	0	0	0	0
	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

TOTAL		TOTAL		TOTAL		OVERALL	
Females	917,024	Males	1,049,173	Unknown	13,516	Total	1,979,713
	46.32%		53.00%		0.68%		100%

Table 10. Aggregate Enrollment Data for Intramural Research Protocols Funded in FY 2001 and Reported in FY 2002

Data Table Comments:

There were more males (1,049,173 or 53%) than females (917,024 or 46.3%) enrolled in aggregate intramural research protocols. Differences in the enrollment of males and females is attributed primarily to improvements in reporting procedures (e.g. ensuring sex/gender declaration and recording at enrollment).

The racial minority group with the largest increase in enrollment is Asian/Pacific Islander - an increase of 50% from FY00 to FY01.

Largest identified racial minority group is Asians at 467,102 or 23.6%.

Smallest identified racial minority group is American Indian/Alaska Native at 17,620 or 0.9%