

2011 Biennial Advisory Council Report Certifying Compliance with Inclusion Guidelines

The National Institute on Drug Abuse (NIDA) Advisory Council has reviewed the implementation of the National Institutes of Health (NIH) Guidelines for inclusion of women and minorities in clinical research, following its meeting on February 2, 2011. The Council determined that NIDA has successfully implemented these NIH Guidelines.

Among the documents reviewed by NIDA Advisory Council were tables showing FY09 and FY10 extramural enrollment data for NIH and NIDA. The overall NIDA minority percentage participation in research in FY09 was 29.9% and in FY10 was 30.4%. Hispanic/Latino research participants are not included in minority calculations. According to the U.S. Census Bureau, Hispanic/Latino individuals are considered an ethnicity and not a race. In FY09, Hispanic/Latino subjects constituted 12.1% of NIDA's extramural enrollment. In FY10, Hispanic/Latino subjects constituted 12.1% as well. Gender data for NIDA show in FY09 45.0% female, 48.1% male and 6.9% unknown. The FY10 data for NIDA was 46.3% female, 48.0% male and 5.7% unknown. The corresponding data for NIH are as follows:

- The NIH minority percentage in FY09 was 30.2% and in FY 10 was 32.1%.
- In FY09, Hispanic/Latino enrollment was 7.4% and in FY10, the Hispanic/Latino enrollment was 15.7%.
- In FY09, NIH total enrollment was 59.8% female, 39.6% male, and 0.7% unknown sex/gender. In FY10, NIH total enrollment was 56.1% female, 43.0% male, and 0.9% unknown sex/gender.

Human subjects enrolled in NIDA Phase III Clinical Trials, reflected in FY09 data, represent 17.7% of NIDA's enrolled extramural subjects. In FY10, NIDA Phase III Clinical Trials represented 14.4% of NIDA's enrolled extramural subjects. The drop in percentage of NIH Phase III Clinical Trials can be attributed to a few factors. First, Phase III Clinical Trials from NIDA's Clinical Trials Network have closed and we are no longer reporting their enrollment. Second, FY2010 is the first year that we have enrollment reporting from the grants awarded under the American Recovery and Reinvestment Act of 2009 (ARRA). ARRA grants account for 4.7% of NIDA's total enrollment. The FY09 data for NIDA Phase III Clinical Trials also show 11.8% of the volunteers enrolled were minorities and 34.4% were female, 36.2% were male, and 29.4% were unknown sex/gender. The FY10 data show 11.9% minorities and 34.5% female, 36.9% male and 28.6% unknown. The reporting of Phase III grants includes a very high number of unknown gender and ethnicity. This can be attributed to a large, 35 year, longitudinal study that did not report enrollment information until 2001. This study includes 22,799 individuals of unknown sex/gender or unknown race/ethnicity. This accounts for 76.4% of the unknown enrollment.

NIDA's Intramural Research Program (IRP) is located in Baltimore, MD. In FY09, African Americans comprised 58.3% of research subjects. The minority enrollment for the IRP was 61.9%. Females comprised 40.4% of the subjects in FY09. In FY10, African Americans comprised 61.4% of research subjects at NIDA's IRP. The total minority enrollment was 64.3%. Females comprised 40.4% of subjects in FY10.

To help ensure that the NIH requirements relating to minority/gender representation are implemented by NIDA, the Grants Management Specialists will not issue a non-competing (type 5) grant award until the minority/gender section of the Program Official's Progress Report is present and contains all required information for each grant and protocol.

The Government Accounting Organization (GAO) Audit of May 2000, entitled "Women's Health – NIH has Increased its Efforts to Include Women in Research," recommended that "the Director of NIH ensure that the agency implements the requirement that phase III clinical trials be designated and carried out to allow for the valid analysis of differences between women and men as fully as it implements other elements of the inclusion policy." The NIDA representative to NIH Tracking and Inclusion Committee is responsible for collecting, coordinating, and reporting this information. NIDA Program Officials responsible for Phase III clinical trial grants continue to be informed of, and are implementing the requirement emphasized in the GAO recommendation. As additional Phase III clinical trials are identified, the appropriate Program Officials and the NIDA representative to the NIH Tracking and Inclusion Committee review the IRG's determination that the project involves a Phase III clinical trial. Ultimate responsibility for NIDA implementation of NIH minority/gender policy at NIDA rests with the Institute Deputy Director. He is assisted by NIDA's NIH Tracking and Inclusion Committee Representative. On a day-to-day basis, many individuals, including Scientific Review Administrators, Program Officials, and Grants Management Specialists, play critical roles in implementing the policies and procedures relative to specific grants.

As of November 2004, Christie Espinoza has been NIDA's representative to the NIH Tracking and Inclusion Committee. Ms. Espinoza has been working with the Office of Extramural Research and the NIH Tracking and Inclusion Committee to ensure that the FY09 and FY10 data tracking human subject research is in compliance with all government regulations. To ensure all NIDA staff is in compliance with these regulations Program Officials with human subject grants have been sent information and resources via e-mail relating to policy and regulations, concerning enrollment of women and minorities in research. Each Program Official works directly with Ms. Espinoza to ensure that their grants meet the policy and regulation requirements.

Data entry into the population tracking database was performed by Christie Espinoza, Quandra Scudder, Aida Klun, and Donna Inman. The data entry staff met four times over the last two years to hold refresher training on the policy as well as technical issues related to maintaining this data for NIDA.

Based on all of the above, the NIDA Advisory Council concluded that NIDA is successfully implementing the NIH Guidelines on minority/gender representation.

Table 1: FY 2009 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE ON DRUG ABUSE

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

Number of Protocols with Enrollment Data: 15

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	16	85	1,340		92	1,074		89	2,696
	0.59%	3.15%	49.7%		3.41%	39.84%		3.3%	43.37%
Male	22	93	1,906		278	1,079		128	3,506
	0.63%	2.65%	54.36%		7.93%	30.78%		3.65%	56.4%
Unknown	0	1	0		0	0		13	14
	0%	7.14%	0%		0%	0%		92.86%	0.23%
Total	38	179	3,246		370	2,153		230	6,216
	0.61%	2.88%	52.22%		5.95%	34.64%		3.7%	100%

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

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

Number of Protocols with Enrollment Data: 773

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	10,809	7,335	46,573	1,261	151,650	14,892	32,054	264,574	221,856	33,099	9,619	264,574
	4.09%	2.77%	17.6%	0.48%	57.32%	5.63%	12.12%	45.29%	83.85%	12.51%	3.64%	45.29%
Male	11,190	8,636	51,027	1,511	159,927	13,293	34,559	280,143	233,067	36,944	10,132	280,143
	3.99%	3.08%	18.21%	0.54%	57.09%	4.75%	12.34%	47.96%	83.2%	13.19%	3.62%	47.96%
Unknown	92	145	656	43	2,101	349	36,025	39,411	3,278	882	35,251	39,411
	0.23%	0.37%	1.66%	0.11%	5.33%	0.89%	91.41%	6.75%	8.32%	2.24%	89.44%	6.75%
Total	22,091	16,116	98,256	2,815	313,678	28,534	102,638	584,128	458,201	70,925	55,002	584,128
	3.78%	2.76%	16.82%	0.48%	53.7%	4.88%	17.57%	100%	78.44%	12.14%	9.42%	100%

Table 2: FY 2010 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE ON DRUG ABUSE

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

Number of Protocols with Enrollment Data: 9

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	16	8	346		90	347		38	845
	1.89%	0.95%	40.95%		10.65%	41.07%		4.5%	31.83%
Male	21	38	891		218	570		72	1,810
	1.16%	2.1%	49.23%		12.04%	31.49%		3.98%	68.17%
Unknown	0	0	0		0	0		0	0
									0%
Total	37	46	1,237		308	917		110	2,655
	1.39%	1.73%	46.59%		11.6%	34.54%		4.14%	100%

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

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

Number of Protocols with Enrollment Data: 960

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	16,549	9,824	60,134	1,575	188,333	18,213	40,169	334,797	281,975	42,581	10,241	334,797
	4.94%	2.93%	17.96%	0.47%	56.25%	5.44%	12%	46.31%	84.22%	12.72%	3.06%	46.31%
Male	16,518	11,717	65,590	1,813	194,104	15,716	40,666	346,124	291,005	44,086	11,033	346,124
	4.77%	3.39%	18.95%	0.52%	56.08%	4.54%	11.75%	47.88%	84.08%	12.74%	3.19%	47.88%
Unknown	112	177	786	59	2,608	452	37,816	42,010	4,054	1,073	36,883	42,010
	0.27%	0.42%	1.87%	0.14%	6.21%	1.08%	90.02%	5.81%	9.65%	2.55%	87.8%	5.81%
Total	33,179	21,718	126,510	3,447	385,045	34,381	118,651	722,931	577,034	87,740	58,157	722,931
	4.59%	3%	17.5%	0.48%	53.26%	4.76%	16.41%	100%	79.82%	12.14%	8.04%	100%

Table 3: FY 2009 Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols

NATIONAL INSTITUTE ON DRUG ABUSE

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards **Number of Protocols with Enrollment Data: 14**

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	16	85	1,340		92	1,074		89	2,696
	0.59%	3.15%	49.7%		3.41%	39.84%		3.3%	43.5%
Male	22	93	1,902		272	1,071		128	3,488
	0.63%	2.67%	54.53%		7.8%	30.71%		3.67%	56.28%
Unknown	0	1	0		0	0		13	14
	0%	7.14%	0%		0%	0%		92.86%	0.23%
Total	38	179	3,242		364	2,145		230	6,198
	0.61%	2.89%	52.31%		5.87%	34.61%		3.71%	100%

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards **Number of Protocols with Enrollment Data: 662**

	Total of All Subjects by Race							Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	10,427	6,696	41,942	1,250	147,508	14,447	31,146	253,416	212,225	31,991	9,200	253,416
	4.11%	2.64%	16.55%	0.49%	58.21%	5.7%	12.29%	44.98%	83.75%	12.62%	3.63%	44.98%
Male	11,145	7,769	48,741	1,496	154,115	13,020	34,308	270,594	224,896	35,780	9,918	270,594
	4.12%	2.87%	18.01%	0.55%	56.95%	4.81%	12.68%	48.03%	83.11%	13.22%	3.67%	48.03%
Unknown	92	145	656	43	2,101	349	36,025	39,411	3278	882	35,251	39,411
	0.23%	0.37%	1.66%	0.11%	5.33%	0.89%	91.41%	6.99%	8.32%	2.24%	89.44%	6.99%
Total	21,664	14,610	91,339	2,789	303,724	27,816	101,479	563,421	440,399	68,653	54,369	563,421
	3.85%	2.59%	16.21%	0.5%	53.91%	4.94%	18.01%	100%	78.17%	12.19%	9.65%	100%

**Table 4: FY 2010 Aggregate Enrollment Data for Extramural Research Protocols
Excluding Male-Only and Female-Only Protocols
NATIONAL INSTITUTE ON DRUG ABUSE**

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

**Number of Protocols
with Enrollment Data: 8**

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	16	8	346		90	347		38	845
	1.89%	0.95%	40.95%		10.65%	41.07%		4.5%	32.04%
Male	21	38	887		212	562		72	1,792
	1.17%	2.12%	49.5%		11.83%	31.36%		4.02%	67.96%
Unknown	0	0	0		0	0		0	0
									0%
Total	37	46	1,233		302	909		110	2,637
	1.4%	1.74%	46.76%		11.45%	34.47%		4.17%	100%

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

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

**Number of Protocols
with Enrollment Data: 816**

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	16,130	9,382	55,193	1,556	183,598	17,693	39,799	323,351	272,134	41,288	9,929	323,351
	4.99%	2.9%	17.07%	0.48%	56.78%	5.47%	12.31%	45.75%	84.16%	12.77%	3.07%	45.75%
Male	16,471	10,836	64,389	1,799	192,186	15,462	40,247	341,390	287,978	42,609	10,803	341,390
	4.82%	3.17%	18.86%	0.53%	56.3%	4.53%	11.79%	48.3%	84.35%	12.48%	3.16%	48.3%
Unknown	112	177	786	59	2,608	452	37,816	42,010	4,054	1,073	36,883	42,010
	0.27%	0.42%	1.87%	0.14%	6.21%	1.08%	90.02%	5.94%	9.65%	2.55%	87.8%	5.94%
Total	32,713	20,395	120,368	3,414	378,392	33,607	117,862	706,751	564,166	84,970	57,615	706,751
	4.63%	2.89%	17.03%	0.48%	53.54%	4.76%	16.68%	100%	79.83%	12.02%	8.15%	100%

Table 5: FY 2009 Aggregate Enrollment Data for Extramural Phase III Research Protocols

NATIONAL INSTITUTE ON DRUG ABUSE

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

Number of Protocols with Enrollment Data: 3

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	0	1	84		14	79		9	187
	0%	0.53%	44.92%		7.49%	42.25%		4.81%	33.75%
Male	1	1	193		55	100		17	367
	0.27%	0.27%	52.59%		14.99%	27.25%		4.63%	66.25%
Unknown	0	0	0		0	0		0	0
									0%
Total	1	2	277		69	179		26	554
	0.18%	0.36%	50%		12.45%	32.31%		4.69%	100%

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

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

Number of Protocols with Enrollment Data: 107

	Total of All Subjects by Race							Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	886	461	1,816	202	22,182	2,010	7,091	34,648	26,935	5,878	1,835	34,648
	2.56%	1.33%	5.24%	0.58%	64.02%	5.8%	20.47%	34.37%	77.74%	16.96%	5.3%	34.37%
Male	1,041	572	2,087	279	22,398	2,121	7,832	36,330	27,108	6,771	2,451	36,330
	2.87%	1.57%	5.74%	0.77%	61.65%	5.84%	21.56%	36.04%	74.62%	18.64%	6.75%	36.04%
Unknown	22	38	44	4	584	56	29,084	29,832	714	267	28,851	29,832
	0.07%	0.13%	0.15%	0.01%	1.96%	0.19%	97.49%	29.59%	2.39%	0.9%	96.71%	29.59%
Total	1,949	1,071	3,947	485	45,164	4,187	44,007	100,810	54,757	12,916	33,137	100,810
	1.93%	1.06%	3.92%	0.48%	44.8%	4.15%	43.65%	100%	54.32%	12.81%	32.87%	100%

**Table 6: FY 2010 Aggregate Enrollment Data for Extramural Phase III Research Protocols
NATIONAL INSTITUTE ON DRUG ABUSE**

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards **Number of Protocols with Enrollment Data: 0**

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female									
Male									
Unknown									
Total									

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

New Form: Total of All Subjects Reported Using the 1997 OMB Standards **Number of Protocols with Enrollment Data: 135**

	Total of All Subjects by Race							Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	885	453	2,146	203	23,133	2,002	7,201	36,023	28,026	6056	1941	36,023
	2.46%	1.26%	5.96%	0.56%	64.22%	5.56%	19.99%	34.5%	77.8%	16.81%	5.39%	34.5%
Male	1,039	574	2,529	277	23,691	2,125	8,320	38,555	28,532	7402	2621	38,555
	2.69%	1.49%	6.56%	0.72%	61.45%	5.51%	21.58%	36.93%	74%	19.2%	6.8%	36.93%
Unknown	22	38	44	4	585	56	29,081	29,830	715	267	28848	29,830
	0.07%	0.13%	0.15%	0.01%	1.96%	0.19%	97.49%	28.57%	2.4%	0.9%	96.71%	28.57%
Total	1,946	1,065	4,719	484	47,409	4,183	44,602	104,408	57,273	13725	33410	104,408
	1.86%	1.02%	4.52%	0.46%	45.41%	4.01%	42.72%	100%	54.85%	13.15%	32%	100%

**Table 7: FY 2009 Aggregate Enrollment Data for Extramural Phase III Research Protocols
Excluding Male-Only and Female-Only Protocols**

NATIONAL INSTITUTE ON DRUG ABUSE

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

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

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female	0	1	84		14	79		9	187
	0%	0.53%	44.92%		7.49%	42.25%		4.81%	33.75%
Male	1	1	193		55	100		17	367
	0.27%	0.27%	52.59%		14.99%	27.25%		4.63%	66.25%
Unknown	0	0	0		0	0		0	0
									0%
Total	1	2	277		69	179		26	554
	0.18%	0.36%	50%		12.45%	32.31%		4.69%	100%

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

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

**Number of Protocols
with Enrollment Data: 88**

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	873	459	1,576	202	21,711	1,942	7,038	33,801	26,164	5,804	1,833	33,801
	2.58%	1.36%	4.66%	0.6%	64.23%	5.75%	20.82%	33.95%	77.41%	17.17%	5.42%	33.95%
Male	1,034	570	1,996	279	22,185	2,073	7,804	35,941	26,772	6,718	2,451	35,941
	2.88%	1.59%	5.55%	0.78%	61.73%	5.77%	21.71%	36.09%	74.49%	18.69%	6.82%	36.09%
Unknown	22	38	44	4	584	56	29,084	29,832	714	267	28,851	29,832
	0.07%	0.13%	0.15%	0.01%	1.96%	0.19%	97.49%	29.96%	2.39%	0.9%	96.71%	29.96%
Total	1,929	1,067	3,616	485	44,480	4,071	43,926	99,574	53,650	12,789	33,135	99,574
	1.94%	1.07%	3.63%	0.49%	44.67%	4.09%	44.11%	100%	53.88%	12.84%	33.28%	100%

**Table 8: FY 2010 Aggregate Enrollment Data for Extramural Phase III Research Protocols
Excluding Male-Only and Female-Only Protocols
NATIONAL INSTITUTE ON DRUG ABUSE**

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

Number of Protocols
with Enrollment Data: 0

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female									
Male									
Unknown									
Total									

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

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

Number of Protocols
with Enrollment Data: 114

	Total of All Subjects by Race							Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	872	451	1,892	202	22,577	1,932	7,143	35,069	27,158	5972	1939	35,069
	2.49%	1.29%	5.4%	0.58%	64.38%	5.51%	20.37%	34.04%	77.44%	17.03%	5.53%	34.04%
Male	1,032	572	2,433	277	23,455	2,075	8,282	38,126	28,167	7338	2621	38,126
	2.71%	1.5%	6.38%	0.73%	61.52%	5.44%	21.72%	37.01%	73.88%	19.25%	6.87%	37.01%
Unknown	22	38	44	4	585	56	29,081	29,830	715	267	28848	29,830
	0.07%	0.13%	0.15%	0.01%	1.96%	0.19%	97.49%	28.95%	2.4%	0.9%	96.71%	28.95%
Total	1,926	1,061	4,369	483	46,617	4,063	44,506	103,025	56,040	13577	33408	103,025
	1.87%	1.03%	4.24%	0.47%	45.25%	3.94%	43.2%	100%	54.39%	13.18%	32.43%	100%

**Table 9: FY 2009 Aggregate Enrollment Data for Intramural Research Protocols
For On-Site and Off-Site Combined**

NATIONAL INSTITUTE ON DRUG ABUSE

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

**Number of Protocols
with Enrollment Data: 0**

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female									
Male									
Unknown									
Total									

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

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

**Number of Protocols
with Enrollment Data: 46**

	Total of All Subjects by Race							Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	70	91	5,072	44	3,080	148	182	8,687	5,621	170	2,896	8,687
	0.81%	1.05%	58.39%	0.51%	35.46%	1.7%	2.1%	40.39%	64.71%	1.96%	33.34%	40.39%
Male	53	109	7,469	45	4,676	217	251	12,820	8,444	212	4,164	12,820
	0.41%	0.85%	58.26%	0.35%	36.47%	1.69%	1.96%	59.6%	65.87%	1.65%	32.48%	59.6%
Unknown	0	0	0	0	0	0	2	2	0	0	2	2
	0%	0%	0%	0%	0%	0%	100%	0.01%	0%	0%	100%	0.01%
Total	123	200	12,541	89	7,756	365	435	21,509	14,065	382	7,062	21,509
	0.57%	0.93%	58.31%	0.41%	36.06%	1.7%	2.02%	100%	65.39%	1.78%	32.83%	100%

**Table 10: FY2010 Aggregate Enrollment Data for Intramural Research Protocols
For On-Site and Off-Site Combined
NATIONAL INSTITUTE ON DRUG ABUSE**

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

**Number of Protocols
with Enrollment Data: 0**

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female									
Male									
Unknown									
Total									

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

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

**Number of Protocols
with Enrollment Data: 53**

	Total of All Subjects by Race							Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	60	70	6,239	5	3,483	177	154	10,188	7,396	153	2639	10,188
	0.59%	0.69%	61.24%	0.05%	34.19%	1.74%	1.51%	39.03%	72.6%	1.5%	25.9%	39.03%
Male	75	136	9,775	8	5,357	228	258	15,837	11,655	290	3892	15,837
	0.47%	0.86%	61.72%	0.05%	33.83%	1.44%	1.63%	60.67%	73.59%	1.83%	24.58%	60.67%
Unknown	0	0	0	0	0	0	78	78	0	0	78	78
	0%	0%	0%	0%	0%	0%	100%	0.3%	0%	0%	100%	0.3%
Total	135	206	16,014	13	8,840	405	490	26,103	19,051	443	6609	26,103
	0.52%	0.79%	61.35%	0.05%	33.87%	1.55%	1.88%	100%	72.98%	1.7%	25.32%	100%