

NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL
REVIEW OF THE NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL
RESEARCH IMPLEMENTATION OF THE NIH POLICY ON THE INCLUSION
OF WOMEN AND MINORITIES IN CLINICAL RESEARCH
FOR FY 2013 AND FY 2014
January 27, 2015

INTRODUCTION

The NIH Revitalization Act of 1993 (PL 103-43) included a provision that women and minorities must be included in all NIH-funded clinical research studies. The Revitalization Act reinforced the existing NIH policies but with four major differences:

- That NIH ensure that women and minorities and their subpopulations be included in all clinical research;
- That women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to allow for valid analyses of differences in intervention effects;
- That cost is not an acceptable reason for excluding these groups; and,
- That NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies.

The NIH Revitalization Act of 1993 stipulates that the advisory councils of each NIH Institute and Center (IC) prepare a biennial report describing activities of the IC staff in complying with the Act as well as results of those activities as reflected in enrollment statistics. This report presents the NIDCR's activities related to fulfilling its responsibilities under the Act.

This report includes Fiscal Years (FY) 2013 and 2014.

STRATEGIES FOR ENSURING POLICY COMPLIANCE WITH INCLUSION GUIDELINES

The NIH Revitalization Act of 1993 and subsequent reports from the Government Accounting Office and Congress have stipulated that NIH and each Institute and Center must ensure that its staff and extramural investigators understand the requirement of the Act and its impact on the conduct of clinical research. Dr. Jane C. Atkinson, Director for the Center for Clinical Research, Division of Extramural Research, provides guidance to Extramural Program Directors about the requirement. Each Program Director also is advised to read the resources provided by the Office of Extramural Research at http://grants2.nih.gov/grants/funding/women_min/women_min.htm. Dr. Atkinson is a member of the Extramural Advisory Working Group that is reviewing NIH compliance with the policy, and the NIH e-Population Tracking Users Group that reviews the tracking system used by NIH to capture the inclusion data and recommends changes as needed. Dr. Atkinson works with Extramural Program Directors during the

year to ensure that the target and enrollment information for grants that require tracking for the inclusion of women and minorities is included in the grant application or in the Type 5 Progress Report. Extramural Program Directors provide assistance to investigators whose applications involve human subjects to ensure they address the inclusion of women and minorities.

As part of the peer review process, each application that involves human subjects must be reviewed for adherence to the inclusion requirements. Review criteria stipulate that the priority score should reflect the appropriateness of the application's efforts to adequately address inclusion issues. In August 2014, the Office of Extramural Research issued updated [Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity and Age in Clinical Research](#) that contained instructions for peer reviewers and for Scientific Review Administrators. This included the need to review NIH-defined Phase III clinical trial research proposals for both inclusion requirements and issues related to the ability of the applicant to conduct valid analyses for sex/gender and/or racial/ethnic groups when appropriate. It also emphasizes that inclusion on the basis of sex/gender, race, and ethnicity, as well as the inclusion of children should be guided by the scientific aims of the study. NIDCR incorporated these guidelines into the review of its clinical research applications. The review requirements of these guidelines are included in all review documents and are discussed with peer reviewers prior to the conduct of a review.

Table A demonstrates the level of compliance with the inclusion policy for extramural grant applications submitted for review in FY 2013 and FY 2014. Of the 923 applications involving human subjects, 877 (95.0%) had enrollment targets that met the inclusion requirements. Of the 46 applications deemed unacceptable (Table A), three awards were made after the enrollment target inclusion issues were resolved (Table B). Table C demonstrates that the vast majority of grants funded by NIDCR enroll both women and men.

Prior to funding, both program and grants management staffs review new grant applications involving human subjects to ensure that a projected target enrollment table is included. If it is not, program staff contacts the investigators to request that this table be provided prior to grants management making the award. Further, in the review of Type 5 progress reports, program staff verifies that an enrollment table has been included and is correctly completed for applications involving human subjects. If the enrollment table is missing, the program director contacts the investigator to correct the error. A continuation award is not made until the enrollment table has been submitted electronically.

Dr. James Melvin, Clinical Director of the Intramural Program at NIDCR, is responsible for overseeing protocol recruitment efforts of Intramural investigators and ensuring they make efforts to include women and minorities in their studies.

Discussions with investigators conducting Phase III clinical trials also include the requirement that analyses by sex/gender and/or racial/ethnic groups be planned and

conducted. One Phase III clinical trial sponsored by NIDCR designed to determine if nonsurgical periodontal treatment reduces levels of glycated hemoglobin (HbA1c) in persons with type 2 diabetes and moderate to advanced periodontitis enrolled at five sites was completed and analyzed in FY 2013 (Engebretson SP, Hyman LG, Michalowicz BS, et al. The effect of nonsurgical periodontal therapy on hemoglobin A1c levels in persons with type 2 diabetes and chronic periodontitis: a randomized clinical trial. JAMA. 2013 Dec 18;310(23):2523-32.). When treatment effects were analyzed, no differences between males and females or by racial group were found.

In October 2014, a new Inclusion Management System (IMS) for reporting sex/gender, race, and ethnicity information as required by the NIH Policy on the Inclusion of Women and Minorities in Clinical Research was released. The system has grantees enter their inclusion data directly into the electronic system. New tools for Program Directors include an electronic means of monitoring the planned versus actual enrollment of individuals on the basis of sex/gender, race, and ethnicity.

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

NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total Number of Applications Reviewed	(#)	294	364	207	305	362	377	87	294
Number of Applications with Human Subjects	(#)	120	134	110	114	129	154	59	103
Number (percent) of Applications approved by IRG as submitted	(#)	116	133	91	110	123	147	59	98
	(%)	96.67%	99.25%	82.73%	96.49%	95.35%	95.45%	100%	95.15%
Number (percent) of Applications with unacceptable <i>minority-only</i> inclusion	(#)	3	0	0	1	1	0	0	1
	(%)	2.5%	0%	0%	0.88%	0.78%	0%	0%	0.97%
Number (percent) of Applications with unacceptable <i>sex/gender-only</i> inclusion	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion	(#)	1	1	19	3	5	7	0	4
	(%)	0.83%	0.75%	17.27%	2.63%	3.88%	4.55%	0%	3.88%
Total Number (percent) of Applications with unacceptable minority inclusion	(#)	4	1	19	4	6	7	0	5
	(%)	3.33%	0.75%	17.27%	3.51%	4.65%	4.55%	0%	4.85%
Total Number (percent) of Applications with unacceptable sex/gender inclusion	(#)	1	1	19	3	5	7	0	4
	(%)	0.83%	0.75%	17.27%	2.63%	3.88%	4.55%	0%	3.88%
Total Number (percent) of unacceptable Applications as submitted	(#)	4	1	19	4	6	7	0	5
	(%)	3.33%	0.75%	17.27%	3.51%	4.65%	4.55%	0%	4.85%

Table B. Extramural Research Awards: Bars-To-Funding and Resolutions
 NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total number of awards	(#)	64	82	30	63	80	93	15	19
Number of awards involving Human Subjects	(#)	19	24	9	18	22	33	0	5
Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted	(#)	19	24	9	17	21	32	0	5
	(%)	100%	100%	100%	94%	95%	97%	0%	100%
Number (percent) of awards where <i>minority-only</i> bar-to-funding was removed by program staff (M_U)	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of awards where <i>sex/gender-only</i> bar-to-funding was removed by program staff (G_U)	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of awards where both minority AND sex/gender bar-to-funding were removed by program staff	(#)	0	0	0	1	1	1	0	0
	(%)	0%	0%	0%	6%	5%	3%	0%	0%
<i>Total Number (percent) of awards where minority bar-to-funding was removed by program staff</i>	(#)	0	0	0	1	1	1	0	0
	(%)	0%	0%	0%	6%	5%	3%	0%	0%
<i>Total Number (percent) of awards where sex/gender bar-to-funding was removed by program staff</i>	(#)	0	0	0	1	1	1	0	0
	(%)	0%	0%	0%	6%	5%	3%	0%	0%
Total Number (percent) of awards where bar-to-funding was removed	(#)	0	0	0	1	1	1	0	0
	(%)	0%	0%	0%	6%	5%	3%	0%	0%

Table C. Inclusion by Sex in All Research Studies
Receiving Funding in FY 2013
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

	Extramural Studies		Intramural Studies	
	Phase III trials*	Other Clinical research**	On-Site	Off-Site
Protocols reporting women only	0	5	2	0
Protocols reporting men only	0	3	1	0
Protocols reporting both women and men	0	72	11	2
Protocols reporting men, women and unknown***	3	9	2	0
Protocols reporting sex composition as unknown only	0	2	0	0
Protocols reporting men and unknown	0	0	0	0
Protocols reporting women and unknown	0	0	0	0
Early Stage studies where enrollment data has not yet submitted	0	66	1	2
Totals	3	157	17	4

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

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

*** Many studies may be generic.

Table C. Inclusion by Sex in All Research Studies
Receiving Funding in FY 2014
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

	Extramural Studies		Intramural Studies	
	Phase III trials*	Other Clinical trials**	On-Site	Off-Site
Protocols reporting women only	0	4	2	0
Protocols reporting men only	0	3	0	0
Protocols reporting both women and men	2	69	13	2
Protocols reporting men, women and unknown***	2	9	2	0
Protocols reporting sex composition as unknown only	0	2	0	0
Protocols reporting men and unknown	0	0	0	0
Protocols reporting women and unknown	0	0	0	0
Early Stage studies where enrollment data has not yet submitted	3	61	1	1
Totals	7	148	18	3

* 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.

ANALYSIS AND INTERPRETATION OF DATA

Analysis of the FY 2013 and FY 2014 NIDCR inclusion data shows that substantial numbers of women, and minorities of both genders, were enrolled in NIDCR-funded clinical research.

All NIDCR Extramural Research Protocols

In FY 2013, 98,425 subjects were enrolled in 94 NIDCR-supported extramural studies that required enrollment monitoring, and in FY 2014 114,284 subjects were enrolled in 91 NIDCR-supported extramural studies that required enrollment monitoring.

Aggregate FY 2013 data (Table 1) revealed 58.55% of enrolled subjects were female, 37.18% were male, and gender was unknown for 4.27%. A similar pattern was present in the aggregate FY 2014 data (Table 2) in that 51.59% of participants were female, 39.28% were male, and gender was unknown for 9.13%. Examination of the aggregate data after exclusion of all male-only and female-only protocols found approximately the same gender distributions for both FY 2013 and FY 2014 (Tables 3 and 4).

Data from the individual protocols indicated that sex/gender reporting was not available in FY 2013 – FY 2014 for some studies utilizing specimens from bio-repositories. Three studies accounted for 3849 of 4200 subjects with no sex/gender information reported in FY 2013 and 9961 of 10,436 subjects reported in FY 2014. These three studies accounted for 92% and 95% of enrolled subjects with unidentified sex/gender reported in FY 2013 and FY 2014, respectively.

In FY 2013 and FY 2014 (Tables 1 and 2), Whites had the highest rates of participation (52.85% in FY 2013 and 65.11% in FY 2014). In FY 2013, Black / African American participation was 18.34%, Asian 10.92% and American Indian / Alaska Native 3.21%. Race was unknown / not reported or refused to identify for 12.55% of participants in FY 2013. In FY 2014, Black / African American participation was 10.10%, Asian 5.96% and American Indian / Alaska Native 3.16%. Race was unknown / not reported or refused to identify for 12.02% of participants in FY 2014. Hispanics represented 11.75% of enrolled subjects in FY 2013 and 13.86% in FY 2014; ethnicity was not reported for 6.9% in FY 2013 and 23.18% in FY 2014. Similar racial and ethnic enrollment trends were observed after exclusion of male-only and female-only protocols (Tables 3 and 4).

Tables 5 and 6 display the total number of subjects enrolled in NIDCR Phase III clinical trials in FY 2013 and FY 2014. In FY 2013, 4078 subjects were enrolled in three Phase III trials, and in FY 2014, 5998 subjects were enrolled in four Phase III trials. The majority of subjects enrolled in these studies were female (62.63% in FY 2013 and 60.65% in FY 2014). Minority participation was higher in Phase III trials than in the aggregate studies because all of these Phase III trials were targeting health disparities populations (American Indian children living on reservations, Hispanic/Latino children living in southern California, and children living in Boston public housing). Notably, 61.28% of participants in FY 2013 and 48.42% in FY 2014 identified themselves as

American Indian / Alaska Native. These individuals were participating in two clinical trials aimed at improving the oral health of American Indian children. Hispanic participation in Phase III trials was high: 35.48% of participants in FY 2013 and 38.66% of participants in FY 2014 identified themselves as Hispanic. In FY 2013, Black or African-American participation in Phase III studies was very low. However, a new health-disparities Phase III trial in FY2014 enrolled many Black/African Americans, making the participation of this population approximately the same as it was for all extramural research.

Tables 9 and 10 display Intramural NIDCR protocol enrollment for FY 2013 – FY 2014. Female participation was higher in Intramural protocols (66.59% in FY 2013; 73.91% in FY 2014) than in Extramural studies, and Hispanic participation was lower (5.81% in FY 2013 and 5.95% in FY 2014). Black / African American enrollment was 12.01% of subjects in FY 2013 and 13.28% in FY 2014, and Whites represented 72.2% of participants enrolled in FY 2013 and 69.96% in FY 2014.

Table 1: FY 2013 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 94

	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	2,184	5,457	10,873	59	31,048	1,353	6,656	57,630	47,520	7,776	2,334	57,630
	3.79%	9.47%	18.87%	0.1%	53.87%	2.35%	11.55%	58.55%	82.46%	13.49%	4.05%	58.55%
Male	964	5,247	7,168	49	19,625	636	2,906	36,595	31,154	3,767	1,674	36,595
	2.63%	14.34%	19.59%	0.13%	53.63%	1.74%	7.94%	37.18%	85.13%	10.29%	4.57%	37.18%
Unknown	10	41	14	0	1,342	1	2,792	4,200	1,401	19	2,780	4,200
	0.24%	0.98%	0.33%	0%	31.95%	0.02%	66.48%	4.27%	33.36%	0.45%	66.19%	4.27%
Total	3,158	10,745	18,055	108	52,015	1,990	12,354	98,425	80,075	11,562	6,788	98,425
	3.21%	10.92%	18.34%	0.11%	52.85%	2.02%	12.55%	100%	81.36%	11.75%	6.9%	100%

Table 2: FY 2014 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 91

	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	2,532	3,417	6,908	100	36,622	2,292	7,084	58,955	42,417	9,853	6,685	58,955
	4.29%	5.8%	11.72%	0.17%	62.12%	3.89%	12.02%	51.59%	71.95%	16.71%	11.34%	51.59%
Male	1,044	3,124	4,387	67	31,089	1,632	3,550	44,893	27,716	5,896	11,281	44,893
	2.33%	6.96%	9.77%	0.15%	69.25%	3.64%	7.91%	39.28%	61.74%	13.13%	25.13%	39.28%
Unknown	35	270	253	0	6,704	76	3,098	10,436	1,816	93	8,527	10,436
	0.34%	2.59%	2.42%	0%	64.24%	0.73%	29.69%	9.13%	17.4%	0.89%	81.71%	9.13%
Total	3,611	6,811	11,548	167	74,415	4,000	13,732	114,284	71,949	15,842	26,493	114,284
	3.16%	5.96%	10.1%	0.15%	65.11%	3.5%	12.02%	100%	62.96%	13.86%	23.18%	100%

Table 3: FY 2013 Aggregate Enrollment Data for Extramural Research Protocols Excluding Male-Only and Female-Only Protocols
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 86

	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	2,181	5,453	10,846	59	30,228	1,347	6,633	56,747	46,682	7,754	2,311	56,747
	3.84%	9.61%	19.11%	0.1%	53.27%	2.37%	11.69%	58.19%	82.26%	13.66%	4.07%	58.19%
Male	964	5,246	7,167	49	19,613	636	2,906	36,581	31,140	3,767	1,674	36,581
	2.64%	14.34%	19.59%	0.13%	53.62%	1.74%	7.94%	37.51%	85.13%	10.3%	4.58%	37.51%
Unknown	10	41	14	0	1,342	1	2,792	4,200	1,401	19	2,780	4,200
	0.24%	0.98%	0.33%	0%	31.95%	0.02%	66.48%	4.31%	33.36%	0.45%	66.19%	4.31%
Total	3,155	10,740	18,027	108	51,183	1,984	12,331	97,528	79,223	11,540	6,765	97,528
	3.23%	11.01%	18.48%	0.11%	52.48%	2.03%	12.64%	100%	81.23%	11.83%	6.94%	100%

Table 4: FY 2014 Aggregate Enrollment Data for Extramural Research Protocols
 Excluding Male-Only and Female-Only Protocols
 NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 84

	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	2,532	3,412	6,877	99	36,357	2,292	7,033	58,602	42,138	9,828	6,636	58,602
	4.32%	5.82%	11.74%	0.17%	62.04%	3.91%	12%	51.44%	71.91%	16.77%	11.32%	51.44%
Male	1,044	3,123	4,386	67	31,087	1,632	3,550	44,889	27,712	5,896	11,281	44,889
	2.33%	6.96%	9.77%	0.15%	69.25%	3.64%	7.91%	39.4%	61.73%	13.13%	25.13%	39.4%
Unknown	35	270	253	0	6,704	76	3,098	10,436	1,816	93	8,527	10,436
	0.34%	2.59%	2.42%	0%	64.24%	0.73%	29.69%	9.16%	17.4%	0.89%	81.71%	9.16%
Total	3,611	6,805	11,516	166	74,148	4,000	13,681	113,927	71,666	15,817	26,444	113,927
	3.17%	5.97%	10.11%	0.15%	65.08%	3.51%	12.01%	100%	62.91%	13.88%	23.21%	100%

Table 5: FY 2013 Aggregate Enrollment Data for Extramural Phase III Research Protocols

NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 3

	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	1,731	1	20	8	682	83	29	2,554	1,756	746	52	2,554
	67.78%	0.04%	0.78%	0.31%	26.7%	3.25%	1.14%	62.63%	68.75%	29.21%	2.04%	62.63%
Male	762	0	12	0	655	62	19	1,510	793	693	24	1,510
	50.46%	0%	0.79%	0%	43.38%	4.11%	1.26%	37.03%	52.52%	45.89%	1.59%	37.03%
Unknown	6	0	1	0	6	1	0	14	5	8	1	14
	42.86%	0%	7.14%	0%	42.86%	7.14%	0%	0.34%	35.71%	57.14%	7.14%	0.34%
Total	2,499	1	33	8	1,343	146	48	4,078	2,554	1,447	77	4,078
	61.28%	0.02%	0.81%	0.2%	32.93%	3.58%	1.18%	100%	62.63%	35.48%	1.89%	100%

Table 6: FY 2014 Aggregate Enrollment Data for Extramural Phase III Research Protocols
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 4			
	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	2,032	11	301	16	925	148	205	3,638	2,355	1,183	100	3,638
	55.85%	0.3%	8.27%	0.44%	25.43%	4.07%	5.63%	60.65%	64.73%	32.52%	2.75%	60.65%
Male	869	11	295	3	879	112	181	2,350	1,170	1,130	50	2,350
	36.98%	0.47%	12.55%	0.13%	37.4%	4.77%	7.7%	39.18%	49.79%	48.09%	2.13%	39.18%
Unknown	3	0	1	0	6	0	0	10	3	6	1	10
	30%	0%	10%	0%	60%	0%	0%	0.17%	30%	60%	10%	0.17%
Total	2,904	22	597	19	1,810	260	386	5,998	3,528	2,319	151	5,998
	48.42%	0.37%	9.95%	0.32%	30.18%	4.33%	6.44%	100%	58.82%	38.66%	2.52%	100%

Table 9: FY 2013 Aggregate Enrollment Data for Intramural Research Protocols For On-Site and Off-Site Combined

NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 18

	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	9 0.27%	209 6.36%	415 12.63%	7 0.21%	2,375 72.25%	23 0.7%	249 7.58%	3,287 66.59%	2,974 90.48%	191 5.81%	122 3.71%	3,287 66.59%
Male	4 0.24%	122 7.41%	178 10.81%	3 0.18%	1,188 72.13%	25 1.52%	127 7.71%	1,647 33.37%	1,488 90.35%	96 5.83%	63 3.83%	1,647 33.37%
Unknown	0 0%	0 0%	0 0%	0 0%	1 50%	0 0%	1 50%	2 0.04%	1 50%	0 0%	1 50%	2 0.04%
Total	13 0.26%	331 6.71%	593 12.01%	10 0.2%	3,564 72.2%	48 0.97%	377 7.64%	4,936 100%	4,463 90.42%	287 5.81%	186 3.77%	4,936 100%

Table 10: FY 2014 Aggregate Enrollment Data for Intramural Research Protocols For On-Site and Off-Site Combined

NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

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: 19

	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	6	204	376	8	1,876	13	211	2,694	2,440	166	88	2,694
	0.22%	7.57%	13.96%	0.3%	69.64%	0.48%	7.83%	73.91%	90.57%	6.16%	3.27%	73.91%
Male	3	83	108	2	673	11	69	949	866	51	32	949
	0.32%	8.75%	11.38%	0.21%	70.92%	1.16%	7.27%	26.04%	91.25%	5.37%	3.37%	26.04%
Unknown	0	0	0	0	1	0	1	2	1	0	1	2
	0%	0%	0%	0%	50%	0%	50%	0.05%	50%	0%	50%	0.05%
Total	9	287	484	10	2,550	24	281	3,645	3,307	217	121	3,645
	0.25%	7.87%	13.28%	0.27%	69.96%	0.66%	7.71%	100%	90.73%	5.95%	3.32%	100%

