2015

NINDS Inclusion of Women and Minorities in Research Report

The NIH Revitalization Act of 1993 (PL 103-43) requires that women and minorities be included in all clinical research studies. The NIH was charged with monitoring clinical research studies to assure compliance. This report serves to document how NINDS has continued to comply with this policy requirement.

National Institute of Neurological Disorders and Stroke

NINDS
NIH
1/7/2015

National Institute of Neurological Disorders and Stroke (NINDS) 2015 Biennial Advisory Council Report Certifying Compliance with Inclusion Guidelines

I Overview

A. NINDS Mission Statement

The National Institute of Neurological Disorders and Stroke (NINDS) conducts and supports research on brain and nervous system disorders. Created by the U.S. Congress in 1950, NINDS is one of the more than two dozen research institutes and centers that comprise the National Institutes of Health (NIH). The NIH, located in Bethesda, Maryland, is an agency of the Public Health Service within the U.S. Department of Health and Human Services. NINDS has occupied a central position in the world of neuroscience for more than 50 years.

More than 600 disorders afflict the nervous system. Common disorders such as stroke, epilepsy, Parkinson's disease, and autism are well-known. Many other neurological disorders are rare-known only to the individuals and families affected, their doctors, and scientists who look to rare disorders for clues to a general understanding of the brain as well as for treatments for specific diseases. Neurological disorders strike an estimated 50 million Americans each year, exacting an incalculable personal toll and an annual economic cost of hundreds of billions of dollars in medical expenses and lost productivity.

The mission of NINDS is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease. To accomplish this goal the NINDS supports and conducts basic, translational, and clinical research on the normal and diseased nervous system. The Institute also fosters the training of investigators in the basic and clinical neurosciences, and seeks better understanding, diagnosis, treatment, and prevention of neurological disorders.

Basic research pursues an understanding of the normal and abnormal structure and activities of the human nervous system. The knowledge gained from this research creates the foundation for diagnosing and treating brain disease. Some important areas of NINDS basic research include: biology of the cells of the nervous system, brain and nervous system development, genetics of the brain, cognition and behavior, neurodegeneration, brain plasticity and repair, neural signaling, learning and memory, motor control and integration, sensory function, and neural channels, synapses, and circuits. The great challenge of modern neuroscience is to translate the remarkable findings of basic science into useful therapies for those who suffer the devastating effects of neurological disorders. To facilitate this translation, NINDS supports many specific research projects and research resources that accelerate preclinical therapy development.

Clinical research applies directly to mechanisms of the diseases of the nervous system which can then be translated into disease detection, prevention, and treatment, such as studies of brain imaging techniques, trials to test new drugs, and development of novel therapies such as stem cell implants and gene transfer. Some key areas of NINDS clinical research include: neurological consequences of AIDS, Alzheimer's disease, brain tumors, developmental disorders, epilepsy, motor neuron diseases, muscular dystrophies, multiple sclerosis, neurogenetic disorders, pain, Parkinson's disease and other neurodegenerative disorders, sleep disorders, spinal cord injury, stroke, and traumatic brain injury.

Most NINDS-funded research is conducted by extramural scientists in public and private institutions, such as universities, medical schools, and hospitals. NINDS intramural scientists, working in the Institute's laboratories, branches, and clinics, also conduct research in most of the major areas of neuroscience and on many of the most important and challenging neurological disorders.

The Institute's interests, however, are not limited to NINDS programs. The Institute collaborates with other NIH components, as well as with other federal agencies, and with voluntary, professional and commercial organizations.

NINDS also is committed to laying the foundation for neuroscience in the years ahead. To achieve this goal, the Institute funds research training and development to help build the next generation of neuroscientists. In addition, NINDS serves as a prime source of neurological information for scientists, clinicians, and the public.

B. History of Inclusion Policy

The NIH Revitalization Act of 1993 (PL 103-43) requires that women and minorities be included in all of its clinical research studies. Under this Act, each Institute is required to prepare a biennial report describing the manner in which the Institute has complied with its tracking obligation on behalf of its Advisory Council.

The October 2001 amendment to the Act clarified several areas of the working Policy on Inclusion of Women and Minorities in Clinical Research, such as the definitions of *clinical research* and the requirements for *Phase 3 clinical trial investigators* to show whether or not clinically important sex/gender and race/ethnicity differences in the intervention effect are to be expected. A significant change in the amendment implemented Office of Management and Budget (OMB) standards which expanded definitions for two ethnic categories (Hispanic or Latino and Not Hispanic) as well as five racial categories: American Indian or Alaska Native, Asian, black or African American, Native Hawaiian or Other Pacific Islander, and white. A glossary of terms for human subjects protection and inclusion issues can be found at *http://grants.nih.gov/grants/peer/tree_glossary.pdf*. The modifications to the OMB

standards were included in the revised Inclusion Enrollment Report and Target/Planned Enrollment Tables (form PHS 398) dated May 2002 and are included at the end of the report as Attachments A and B.

Since 1995, a trans-NIH database has been used to track and monitor inclusion for both extramural and intramural research projects. Data from each study protocol are entered into the NIH tracking database for research grants, centers, program projects, research contracts, and cooperative agreements that involve human subjects. Most grants or contracts consist of a single protocol; however, larger studies may include more than one protocol. This situation occurs most often in center (P50) or program project grants (P01) that involve more than one clinical project, or in clinical trials including more than one treatment paradigm. Although the law requires inclusion of women and minority subjects in all clinical studies, the NIH tracking database allows exceptions for certain circumstances, such as small sample size (< 10 subjects), duplication of reporting, parent records, secondary analysis, early stage technology development, not clinical research, and IC defined reason. In addition, several grant mechanisms are exempt from enrollment tracking, including Clinical and Translational Science Awards (CTSA), training grants, fellowships, and grants for resources or construction.

II Strategies for Ensuring Policy Compliance with Inclusion Guidelines

A. Peer Review

The following processes are utilized at the NINDS to address inclusion of women and minorities in clinical research. The NIH peer review system is a mandated statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research Development Contract Proposals" (42 CFR Part 52h). The NIH system is a two phase review system where the first phase consists of a review by primarily non-federal scientists who have expertise in the relevant science and current research area carried out by a Scientific Review Group. The second level of review is conducted by each Institute or Center's Council.

In the initial peer review process, grants are reviewed either by the Center for Scientific Review (CSR) or an individual IC review group. Review criteria have been issued for the evaluation of research applications received and can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html.

While the review of the inclusion plan of Women, Minorities and Children is included in the peer review process for all clinical research, Phase 3 clinical trials are required to have inclusion analysis plans to inform enrollment targets. Reviewers assess inclusion plans, the

appropriateness of planned exclusions, and whether the recruitment plan is sufficient. The summary statement documents any concerns raised during peer review. Before each Council meeting, Program Directors examine reviewers' comments on unacceptable inclusion goals and resolve issues in writing with the investigators. Council members may question Program Staff about the resolution of any issues brought up by reviewers prior to recommending grants for funding.

The individual Program Director reviews and approves target and enrollment data for both new grants and yearly non-competing continuation applications within their portfolios.

Post-award, Program Directors review enrollment data submitted in the annual progress reports and determine whether the enrollment targets for gender and minority inclusion are scientifically appropriate. For clinical trials, inclusion issues may also be discussed by the Data and Safety Monitoring Boards (DSMBs) or other oversight groups. To ensure accurate reporting in compliance with the NIH Inclusion Guidelines, investigators are contacted by Program Staff to clarify any discrepancies and resolve any issues before grant funds are awarded.

The NIH Inclusion Monitoring System (IMS) allows access to Institute records and cumulative reports, enabling program staff to track enrollment data in their grant portfolios. With the advent of electronic submission, target and enrollment tables are now automatically entered into the population tracking system which has reduced data entry errors seen in the past.

At NINDS, staff in the Office of Clinical Research provide oversight on gender and minority tracking activities by assisting program staff and grants management as needed, including issues on tracking exemptions and making any necessary changes to the tracking codes in the population tracking database.

B. Staff Training on the Utilization of the Tracking System within NINDS

There are several documents that provide guidance located on the NIH eRA intranet, including a NIH staff only user guide and several "Quick Tips" documents, created to assist with the actual entry of data to the population tracking system. Staff in the Office of Clinical Research also provide assistance to program staff, grants management specialists, and has provided training to new staff on women/minority inclusion reporting policies and population tracking procedures.

III NINDS Aggregate Enrollment Data

For the 2013-2014 enrollment reporting period, NINDS is reporting inclusion enrollment for clinical research projects via the NIH population tracking application linked to the NIH IMPAC II database. The data in this report only includes protocols where both tracking was required and actual enrollment numbers have been provided. Human subjects research where a tracking exception has been granted OR tracking is required but enrollment has not commenced, is not included in this analysis.

All Extramural Tracked Research

In fiscal year 2013, NINDS-funded Extramural Clinical Research involved 352 tracked domestic protocols and 15 tracked foreign protocols with a total participant enrollment of 379,643 and 29,379 persons respectively. In fiscal year 2014, there were 316 tracked domestic extramural protocols and 21 tracked foreign protocols with a total participant enrollment of 315,502 and 25,314 person s respectively. The proportion of women (54%), non-whites* (24-25%), and Hispanics (9%) remained stable during this two year time period. The complete aggregate enrollment data for NINDS Extramural Research Projects for fiscal years 2013 and 2014 are presented in Tables 1 and 2.

Phase 3 Tracked Research

In fiscal year 2013, NINDS-funded Phase 3 Research involved 18 tracked domestic protocols and 6 tracked foreign protocols with a total participant enrollment of 15,289 and 3,126, respectively. In fiscal year 2014, there were 12 tracked domestic phase 3 protocols and 5 tracked foreign protocols with a total participant enrollment of 9,004 and 1,027, respectively. The proportion of women in domestic protocols was 40% in FY 2013 and 42% in FY 2014. The proportion of non-whites in domestic protocols was 22% in FY 2013 and 20% in FY 2014. The proportion of Hispanics in domestic protocols was 9% in FY 2013 and 10% in FY 2014. The complete aggregate enrollment data for NINDS Extramural Phase 3 Research Projects for fiscal years 2013 and 2014 are presented in Tables 3 and 4.

Intramural Tracked Research

In fiscal year 2013, NINDS-funded Intramural Research involved 111 domestic protocols and 1 foreign protocol with a total participant enrollment of 17,555 and 701, respectively. In fiscal year 2014, there were 112 domestic intramural protocols and 1 foreign protocol with a total participant enrollment of 18,300 and 701, respectively. The proportion of women in domestic protocols was 49% in both FY 2013 and 2014. The proportion of non-whites in domestic protocols was 17% in both FY 2013 and 2014. The proportion of Hispanics in domestic protocols was 5% in FY 2013 and 6% in FY 2014. The complete aggregate

enrollment data for NINDS Intramural Research Projects for fiscal years 2013 and 2014 are presented in Tables 5 and 6. In addition, the complete aggregate enrollment data for all clinical research projects (extramural plus intramural) for fiscal years 2013 and 2014 are presented in Tables 7 and 8.

* Non-Whites: Sum of the subjects enrolled under American Indian/Alaska Native, Asian, black or African American, Hawaiian/Pacific Islander, and More than One Race

Table 1: FY2013 Aggregate Enrollment Data for All Extramural Research Protocols

	Domestic		Domestic + Foreign	
Female	203,873	54%	220,249	54%
Male	165,150	44%	177,491	43%
Unknown/Not Reported (Gender)	10,620	3%	11,282	3%
American Indian/Alaska Native	1,956	1%	1,972	0%
Asian	29,620	8%	30,401	7%
Hawaiian/Pacific Islander	1,126	0%	1,144	0%
Black or African American	46,666	12%	47,295	12%
White	264,901	70%	290,066	71%
More Than One Race	11,435	3%	12,104	3%
Unknown/Not Reported (Race)	23,939	6%	26,040	6%
Non-White	90,803	24%	92,916	23%
Hispanic	37,405	10%	38,518	9%
Not-Hispanic	299,347	79%	326,483	80%
Unknown/Not Reported (Ethnicity)	42,891	11%	44,021	11%
Total Participants	**379,643**		**409,022**	
Total Protocol Records	**352**		**367**	

Table 2: FY2014 Aggregate Enrollment Data for All Extramural Research Protocols

	Domestic		Domestic + Foreign	
Female	166,966	53%	184,377	54%
Male	142,648	45%	149,512	44%
Unknown/Not Reported (Gender)	5,888	2%	6,927	2%
American Indian/Alaska Native	2,066	1%	2,070	1%
Asian	27,343	9%	29,200	9%
Hawaiian/Pacific Islander	1,079	0%	1,217	0%
Black or African American	37,499	12%	38,402	11%
White	214,900	68%	236,117	69%
More Than One Race	10,746	3%	10,999	3%
Unknown/Not Reported (Race)	21,869	7%	22,811	7%
Non-White	78,733	25%	81,888	24%
Hispanic	30,825	10%	31,502	9%
Not-Hispanic	244,313	77%	267,932	79%
Unknown/Not Reported (Ethnicity)	40,364	13%	41,382	12%
Total Participants	**315,502**		**340,816**	
Total Protocol Records	**316**		**337**	

Table 3: FY2013 Aggregate Enrollment Data for Extramural Phase 3 Research Protocols

	Domestic		Domestic + Foreign	
Female	6,183	40%	7,181	39%
Male	9,098	60%	11,221	61%
Unknown/Not Reported (Gender)	8	0%	13	0%
American Indian/Alaska Native	67	0%	72	0%
Asian	474	3%	498	3%
Hawaiian/Pacific Islander	64	0%	82	0%
Black or African American	2,568	17%	2,605	14%
White	11,530	75%	13,905	76%
More Than One Race	166	1%	699	4%
Unknown/Not Reported (Race)	420	3%	554	3%
Non-White	3,339	22%	3,956	21%
Hispanic	1,382	9%	2,125	12%
Not-Hispanic	13,411	88%	15,784	86%
Unknown/Not Reported (Ethnicity)	496	3%	506	3%
Total Participants	**15,289**		**18,415**	
Total Protocol Records	**18**		**24**	

Table 4: FY2014 Aggregate Enrollment Data for Extramural Phase 3 Research Protocols

	Domestic		Domestic + Foreign	
Female	3,776	42%	4,204	42%
Male	5,225	58%	5,822	58%
Unknown/Not Reported (Gender)	3	0%	5	0%
American Indian/Alaska Native	42	0%	45	0%
Asian	294	3%	630	6%
Hawaiian/Pacific Islander	24	0%	25	0%
Black or African American	1,309	15%	1,317	13%
White	7,088	79%	7,750	77%
More Than One Race	92	1%	100	1%
Unknown/Not Reported (Race)	155	2%	164	2%
Non-White	1,761	20%	2,117	21%
Hispanic	915	10%	957	10%
Not-Hispanic	7,748	86%	8,714	87%
Unknown/Not Reported (Ethnicity)	341	4%	360	4%
Total Participants	**9,004**		**10,031**	
Total Protocol Records	**12**		**17**	

Table 5: FY2013 Aggregate Enrollment Data for Intramural Research Protocols

	Domestic		Domestic + Foreign	
Female	8,616	49%	8,814	48%
Male	8,934	51%	9,437	52%
Unknown/Not Reported (Gender)	5	0%	5	0%
American Indian/Alaska Native	30	0%	30	0%
Asian	864	5%	864	5%
Hawaiian/Pacific Islander	23	0%	23	0%
Black or African American	1,848	11%	2,549	14%
White	13,616	78%	13,616	75%
More Than One Race	159	1%	159	1%
Unknown/Not Reported (Race)	1,015	6%	1,015	6%
Non-White	2,924	17%	3,625	20%
Hispanic	936	5%	936	5%
Not-Hispanic	16,187	92%	16,888	93%
Unknown/Not Reported (Ethnicity)	432	2%	432	2%
Total Participants	**17,555**		**18,256**	
Total Protocol Records	**111**		**112**	

Table 6: FY2014 Aggregate Enrollment Data for Intramural Research Protocols

	Domestic		Domestic + Foreign	
Female	9,000	49%	9,198	48%
Male	9,283	51%	9,786	52%
Unknown/Not Reported (Gender)	17	0%	17	0%
American Indian/Alaska Native	30	0%	30	0%
Asian	850	5%	850	4%
Hawaiian/Pacific Islander	25	0%	25	0%
Black or African American	1,939	11%	2,640	14%
White	14,185	78%	14,185	75%
More Than One Race	188	1%	188	1%
Unknown/Not Reported (Race)	1,083	6%	1,083	6%
Non-White	3,032	17%	3,733	20%
Hispanic	1,010	6%	1,010	5%
Not-Hispanic	16,829	92%	17,530	92%
Unknown/Not Reported (Ethnicity)	461	3%	461	2%
Total Participants	**18,300**		**19,001**	
Total Protocol Records	**112**		**113**	

Table 7: FY2013 Aggregate Enrollment Data for All Clinical Research Protocols

	Domestic		Domestic + Foreign	
Female	212,489	53%	229,063	54%
Male	174,084	44%	186,928	44%
Unknown/Not Reported (Gender)	10,625	3%	11,287	3%
American Indian/Alaska Native	1,986	1%	2,002	0%
Asian	30,484	8%	31,265	7%
Hawaiian/Pacific Islander	1,149	0%	1,167	0%
Black or African American	48,514	12%	49,844	12%
White	278,517	70%	303,682	71%
More Than One Race	11,594	3%	12,263	3%
Unknown/Not Reported (Race)	24,954	6%	27,055	6%
Non-White	93,727	24%	96,541	23%
Hispanic	38,341	10%	39,454	9%
Not-Hispanic	315,534	79%	343,371	80%
Unknown/Not Reported (Ethnicity)	43,323	11%	44,453	10%
Total Participants	**397,198**		**427,278**	
Total Protocol Records	**463**		**479**	

Table 8: FY2014 Aggregate Enrollment Data for All Clinical Research Protocols

	Domestic		Domestic + Foreign	
Female	175,966	53%	193,575	54%
Male	151,931	46%	159,298	44%
Unknown/Not Reported (Gender)	5,905	2%	6,944	2%
American Indian/Alaska Native	2,096	1%	2,100	1%
Asian	28,193	8%	30,050	8%
Hawaiian/Pacific Islander	1,104	0%	1,242	0%
Black or African American	39,438	12%	41,042	11%
White	229,085	69%	250,302	70%
More Than One Race	10,934	3%	11,187	3%
Unknown/Not Reported (Race)	22,952	7%	23,894	7%
Non-White	81,765	24%	85,621	24%
Hispanic	31,835	10%	32,512	9%
Not-Hispanic	261,142	78%	285,462	79%
Unknown/Not Reported (Ethnicity)	40,825	12%	41,843	12%
Total Participants	**333,802**		**359,817**	
Total Protocol Records	**428**		**450**	

IV NINDS Activities Related to Inclusion in Clinical Research

Workshops/Initiatives

Improving Neurological Subject (and Provider) Participation In the Research Enterprise (INSPIRE) Workshop

In June 2013, the NINDS held a workshop on Improving Neurological Subject (and Provider) Participation In the Research Enterprise (INSPIRE). The purpose of the workshop was to address the growing challenge of engaging patients in clinical research and to develop tools to enhance recruitment and retention to neurological clinical studies. The workshop brought together more than 125 investigators, clinicians, clinical coordinators, project and data managers, biostatisticians, communications specialists, patients and patient advocates, as well as NIH and FDA staff. Over the course of two days, attendees heard from leading experts on patient-centered research, the state of the clinical research enterprise and changing attitudes towards public engagement. They also participated in working sessions focused on a wide range of issues that can impact patient recruitment including protocol design and data collection; communication and outreach; recruitment and retention planning and study management. During interactive session, participants shared model plans, resources, training programs and experiences (both positive and negative), and developed recommendations that could serve as action plans for future researchers, clinicians, patients and patient advocates.

A component of the workshop addressed recruitment of minorities and women with the following topics:

- -Perspectives on Integrating the Needs of Minority and Underserved Populations When Designing Research Questions and Protocols (Dorothy Edwards, PhD)
- -Structural and Systemic Barriers to the Inclusion of Minorities in Neurological Research (Bernadette Boden-Albala, PhD)
- -Inclusion, Community Engagement, and the RECRUIT Study (Barbara Tilley, PhD)

National Initiative for Minority Involvement in Neurological Clinical Trials
PI: Bernadette Boden-Albala, Ph.D.

This is a grant funded by NIMHD and NINDS with the goal to develop and test tools, procedures and guidelines to improve minority recruitment and retention in neurological clinical trials. The resources developed by this project will be available to NIH-funded investigators to aid with minority recruitment in their studies.

Analyses of recently completed Phase 3 studies to determine whether clinically significant differences were found based on race, ethnicity and/or gender:

A. **Field Administration of Stroke Therapy-Magnesium Trial (FAST-MAG)**
   PI: Jeffrey Saver, M.D.
   FAST-MAG was an acute, pre-hospital stroke treatment trial that enrolled and treated patients with an acute stroke in the ambulance using exception from informed consent. Twenty-four percent of the enrolled population was Hispanic in origin and 13% were African American.

B. **Interdisciplinary Comprehensive Arm Rehab Evaluation (I-CARE) Stroke Initiative**
   PI: Carolee Winstein, Ph.D.
   I-CARE was a stroke rehabilitation study that included sites in Atlanta, Washington DC and Los Angeles. Overall, 42% of the enrolled population was African-American and 10% were Hispanic (largely enrolled in the California sites).

Funding of ongoing studies targeting ethnic/racial variations:
(These studies may be informative for future Phase 3 inclusion planning efforts.)

A. **Ethnic/Racial Variation in Intracerebral Hemorrhage (ERICH) Study**
   PI: Daniel Woo, M.D.

   The ERICH study is a large, case-control study of intracerebral hemorrhage (ICH) with particular emphasis on recruitment of Black, White, and Hispanic populations for the identification of genetic and epidemiological risk factors for ICH and outcomes after ICH. They found high rates of infection in hemorrhage (which was also associated with poor outcome) and infection was associated with being black.

   Infection after intracerebral hemorrhage: risk factors and association with outcomes in the ethnic/racial variations of intracerebral hemorrhage study.
   Lord AS, Langefeld CD, Sekar P, Moomaw CJ, Badjatia N, Vashkevich A, Rosand J, Osborne J, Woo D, Elkind MS. Stroke. 2014 Dec; 45 (12):3535-42

B. **Reasons for Geographic and Racial Differences in Stroke (REGARDS)**
   PI: George Howard, Dr. PH.

REGARDS is a national, population-based, longitudinal study of black and white participants aged 45 or older. The goal is to elucidate racial disparities involving stroke by monitoring incident stroke and cognitive impairment. Between 2003 and 2007, the study had enrolled 30,000 participants.

C. Northern Manhattan Study (NOMAS)
PI: Ralph Sacco, M.D.
NOMAS is a population-based study in a tri-ethnic community (black, white, Caribbean Hispanic). The study consists of a prospective evaluation of vascular risk factors in over 3000 participants, 1300 with a brain MRI. The study team will assess stroke, dementia, cognitive trajectories, and imaging biomarkers with a median follow-up of about 15 years.

Evaluation/monitoring of inclusion analysis plans for recently-funded Phase 3 studies:

Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST 2)
PI: Thomas Brott, M.D.

Minimally Invasive Surgery Plus rt-PA for Intracerebral Hemorrhage Evacuation (MISTIE III)
PI: Daniel Hanley, M.D.

Established Status Epilepticus Treatment Trial (ESETT)
PI: Jaideep Kapur, Ph.D.

Safety, Tolerability, and Efficacy Assessment of Isradipine CR for P (STEADY-PD3)
PI: Tanya Simuni, M.D.

Additional NINDS Activities Include:

-Incorporation of inclusion discussions in meetings and workshops, clinical trial start-up meetings, OCR Recruitment Workshop planning, network executive committee calls, milestone planning/evaluation

-Representation and involvement in the Inclusion Operating Procedures Workgroup (IOPW) and EAWG Subcommittee on Inclusion Governance (E-SIG)

- Discussion of inclusion of minorities in NINDS studies at Health Disparities Working Group meetings which involve Program Directors from across the NINDS Division of Extramural Research

ATTACHMENT A

Principal Investigator/Program Director (Last, First, Middle):

Targeted/Planned Enrollment Table

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

Study Title:

Total Planned Enrollment:

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

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

ATTACHMENT B

Principal Investigator/Program Director (Last, First, Middle):

Inclusion Enrollment Report

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

Study Title: _____

Total Enrollment: _____ **Protocol Number:** _____

Grant Number: _____

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
	Sex/Gender			
Ethnic Category	**Females**	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*				*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

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