

National Cancer Advisory Board

Biennial Review of Inclusion of Women and Minorities in Clinical Research

February 2007

NIH Policy on Inclusion of Women and Minorities in Clinical Research

Why does NIH have this policy?

- Mandated by Congress in 1993, Public Law 103-43.
- Ethical principle of justice and importance of balancing research burdens and benefits.

Public Law PL 103-43

- Women and minorities must be included in all clinical research studies.
- Women and minorities must be included in Phase III clinical trials, and the trial must be designed to permit valid analysis.
 - For the purpose of this policy, Valid Analysis means an unbiased assessment that does not require high statistical power and should be conducted for both large and small studies.

Public Law PL 103-43

- Cost is not allowed as an acceptable reason for exclusion.
- NIH supports outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies.

NIH Revitalization Act of 1993

“The Advisory Council of each National Institute shall prepare biennial reports describing the manner in which the institute has complied with this section.”

- Done in odd-numbered years.

NIH Report Approach

A summary report is prepared centrally by the NIH Office of Research on Women's Health and includes statement that the NCAB reviews.

- NCI procedures for implementation of the NIH policy for inclusion of women and minorities in clinical studies.
- The results of that implementation.
- NCI compliance.

NCI Coordination

Division of Extramural Activities

Implements Inclusion Policy at NCI

- Institute-wide coordination and communication
- Accrual Working Group –Division Reps
- Information, Training, Problem Solving

NCI Procedures for Implementation of NIH Policy

POLICY DISSEMINATION

- HSAs work with applicants to disseminate requirements (*NIH Guide and NCI and NIH Websites*).
- NCI extramural staff are kept up-to-date via trans-NIH education programs and desktop distribution of policies and procedures.

NCI Procedures for Implementation of NIH Policy

PRE-AWARD ACTIVITIES

- Peer reviewers receive instruction on policies and evaluate inclusion plans.
- Where concerns are noted, bars to award are put in place. NCI staff work with applicants to ensure appropriate revisions are made.
- Applications with bars are identified in a closed NCAB session, and a subsequent resolution is reported.

NCI Procedures for Implementation of NIH Policy

POST-AWARD MONITORING

- Awardees report cumulative accrual annually.
- Progress of studies and cumulative accruals are reviewed by Program Directors.
- Target and enrollment numbers are entered into the NIH Population Tracking application.
- Staff provide oversight, advice, and assistance and work with awardees to disseminate findings and encourage new studies.

NCI Procedures for Implementation of NIH Policy

AGGREGATE REPORTING

- NIH requires a format that aggregates all Phase III clinical trials whether treatment, behavioral, or epidemiologic observation.
 - Individual clinical trials vary considerably.
 - Large population-based screening trials dominate aggregate data.

NIH Policy for Inclusion Updated to Meet New OMB Standards

OMB Directive 15 issued in 1997:

- Created racial and ethnic standards for Federal statistics and administrative reporting.
- Effective date no later than January 1, 2003.

Change in Requirements for Population Types

- Made changes in categories to correspond to the 2000 census data collection, i.e., “Hispanic” is an ethnic category.
- Data now to be collected in 3 categories (ethnicity, race, and sex/gender) rather than 2 categories (race and sex/gender).
- Old form versus new form creates transition challenges.

Change in Reporting Categories

	Old Form	New Form
1. Ethnicity		Hispanic, Non-Hispanic
2. Race	Asian	Asian
	Black	Black
	Hispanic	Hawaiian/Pacific Islander
	Native American and Alaska Native	Native American and Alaska Native
	White	White
	Unknown (or Other)	More Than One Race
		Unknown (or Other)

Instructions in PHS 398

Inclusion of women and minorities sections **must** include:

- Subject selection criteria and rationale.
- Rationale for any exclusions.
- Enrollment dates (start and end).
- Outreach plans for recruitment.
- Proposed composition using new tables.

Accrual to NCI Clinical Trials

- Data include epidemiological, population-based interventions and therapeutic trials according to the NIH definition of clinical research.
- Subset analyses by race, ethnicity, and sex/gender are required of all Phase III clinical trials with initial funding after 1995.
- Current reporting cycle covers data reported in FY2005 and 2006, which represents subjects enrolled in FY2004 and 2005.

Requirements for NIH-Defined Phase III Clinical Trials

Definition: Broadly based prospective Phase III clinical investigation,

- usually involving several hundred or more human subjects,
- for the purpose of evaluating an experimental intervention or comparing two or more existing treatments.
- Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

US 2000 Census Data

		American Indian	Asian	Black	White	Other
Race alone	#	2.5	10.2	34.7	211.5	19.4
	%	0.9	3.6	12.3	75.1	6.7
*More than one Race	#	4.1	11.9	36.4	216.9	
	%	1.5	4.2	12.9	77.1	

Hispanic 35.3 million = 12.5% (47.9% White)

Total population 281.4 million

*** 2.4% of respondents**

US Cancer Incidence Rates*

	All	American Indian	Asian	Black	White	Hispanic
Rate per 100,000	471.3	325.8	315.6	504.4	478.4	353.1
Estimated Cases, in thousands	1,326	8	32	175	1,012	125
Estimated Percent		0.6	2.4	13.2	76.3	9.4

*US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

Enrollment for Extramural Research Studies by Sex/Gender

2005
2,117 Studies

Sex/Gender	Enrolled	Percent
Female	3,344,210	81.5
Male	732,562	17.9
Unknown	25,171	0.6
Total	4,101,943	100.0

2006
2,447 Studies

Sex/Gender	Enrolled	Percent
Female	3,801,558	83.3
Male	728,295	16.0
Unknown	32,591	0.7
Total	4,562,444	100.0

**Sex/Gender Enrollments
without All Male and All Female Studies
2006—1,748 Studies***

Sex/Gender	Enrollment	Percent of Total	US Cancer Incidence**
Female	657,279	53.2	43.7
Male	545,386	44.2	56.3
Other/Unknown	32,591	2.6	
Total	1,235,256	100.0	100.0

*Subset of studies reported for 2006; Studies include both Male and Female enrollment.

**US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

FY 2005 Enrollment Extramural Research Studies Old Format - 615 Studies

Race/Ethnicity	Number on Study	Percent on Study	US Cancer Incidence**
White	183,329	78.5	76.3
Black	17,649	7.6	13.2
Other	13,142	5.6	
Asian/ Pacific Islander	9,327	4.0	2.4
Hispanic	9,113	3.9	(9.4)*
American Indian/ Alaska Native	814	0.4	0.6
Total	233,374	100	100.00

*Percent Hispanic incidence included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

**FY 2005 Enrollment
Extramural Research Studies
New Format - 1,502 Studies**

Race/Ethnicity	Count	Percent of Total	US Cancer Incidence*
White	2,527,716	65.3	76.3
Unknown/Not Reported	395,093	10.2	
Asian	329,734	8.5	2.4
Black or African American	308,597	8.0	13.2
Hispanic or Latino American	(286,884)	(7.4)	(9.4)
Indian/Alaska Native	250,034	6.5	0.6
More Than One Race	36,087	0.9	
Native Hawaiian/ Pacific Islander	21,308	0.6	
Total	3,868,569	100.0	100.0

*US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

FY 2006 Enrollment Extramural Research Studies Old Format - 599 Studies

Race/Ethnicity	Number on Study	Percent on Study	US Cancer Incidence**
White	182,143	82.9	76.3
Other	13,652	6.2	
Black	13,251	6.0	13.2
Hispanic	6,483	3.0	(9.4)*
Asian/Pacific Islander	3,544	1.6	2.4
American Indian/ Alaska Native	627	0.3	0.6
Total	219,700	100.0	100.0

*Percent Hispanic US Cancer Incidence included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

FY 2006 Enrollment Extramural Research Studies New Format - 1,848 Studies

Race/Ethnicity	Count	Percent of Total	US Cancer Incidence*
White	2,866,135	66.0	76.3
Unknown/Not Reported	529,602	12.2	
Asian	518,571	11.9	2.4
Black or African American	324,326	7.5	13.2
Hispanic or Latino	(303,421)	(7.0)	(9.4)
American Indian/ Alaska Native	50,466	1.2	0.6
More Than One Race	35,555	0.8	
Native Hawaiian/ Pacific Islander	18,089	0.4	
Total	4,342,744	100.0	100.0

*US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

Ethnic Categories New Format FY 2005 and 2006

	FY2005		FY2006		U.S. Cancer Incidence**
	1,502 Studies		1,848 Studies		
	Count	Percent of Total	Count	Percent of Total	Percent of Total
Not Hispanic	3,180,289	82.2	3,452,186	79.5	90.6*
Unknown or Not Reported	401,396	10.4	587,137	13.5	
Hispanic or Latino	286,884	7.4	303,421	7.0	9.4
Total	3,868,569	100.0	4,342,744	100.0	100.0

*Includes non-hispanic and those of unknown or not reported ethnicity.

**US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

**FY 2005 - NCI Enrollment
Extramural Phase III Research Studies
Old Format - 158 Studies**

Race/Ethnicity	Number On Study	Percent On Study	US Cancer Incidence*
White	130,979	82.2	76.3
Black	14,265	9.0	13.2
Hispanic	7,581	4.8	(9.4)
Unknown/Other	2,973	1.9	
Asian/Pacific Islander	2,898	1.8	2.4
American Indian/ Alaska Native	591	0.4	0.6
Total	159,287	100.0	100.0

*US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

**FY 2005 - NCI Enrollment
Extramural Phase III Research Studies
New Format - 92 Studies**

Race/Ethnicity	Count	Percent of Total
White	38,617	84.1
Unknown/Not Reported	2,123	4.6
Asian	1,968	4.3
Black or African American	1,920	4.2
Hispanic or Latino	(1,866)	(4.1)
More Than One Race	836	1.8
Amer. Indian/Alaska Native	253	0.6
Hawaiian/Pacific Islander	217	0.5
Total	45,934	100.0

FY 2006 - NCI Enrollment Extramural Phase III Research Studies Old Format - 171 Studies

Race/Ethnicity	Number On Study	Percent On Study	US Cancer Incidence*
White	103,827	82.0	76.3
Black	10,014	7.9	13.2
Hispanic	4,959	3.9	(9.4)
Unknown/Other	4,856	3.8	
Asian/Pacific Islander	2,496	2.0	2.4
American Indian/ Alaska Native	425	0.3	0.6
Total	126,577	100.0	100.0

*US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

**FY 2006 - NCI Enrollment
Extramural Phase III Research Studies
New Format - 126 Studies**

Race/Ethnicity	Count	Percent of Total
White	55,655	80.7
Unknown/Not Reported	5,201	7.5
Black or African American	3,724	5.4
Hispanic or Latino	(3,312)	(4.8)
Asian	2,635	3.8
More Than One Race	995	1.4
Amer. Indian/ Alaska Native	416	0.6
Native Hawaiian/ Pacific Islander	312	0.5
Total	68,938	100.0

FY 2005 and 2006 NCI Enrollment Extramural Phase III Research Studies by Sex/Gender

FY 2005
250 Trials

Sex/Gender	Count	Percent of Total
Female	113,612	55.4
Male	91,277	44.5
Unknown	332	0.2
Total	205,211	100.0

FY 2006
297 Trials

Sex/Gender	Count	Percent of Total
Female	121,811	62.3
Male	72,404	37.0
Unknown	1,300	0.7
Total	195,515	100.0

Intramural Research Studies FY 2005 – Old Format Data – 176 Studies

Race/Ethnicity	Number on Study	Percent of Total
White	238,500	55.7
Asian/Pacific Islander	128,287	30.0
Unknown/Other	39,568	9.2
Black	11,833	2.8
Hispanic	9,209	2.2
American Indian/Alaska Native	704	0.2
Total	428,101	100.0

Intramural Research Studies FY 2005 New Format Data – 191 Studies

Ethnicity	Count	Proportion on Trials
Not Hispanic or Latino	901,611	97.0
Hispanic or Latino	16,688	1.8
Not Reported/Unknown	11,444	1.2
Total	929,743	100.0

Intramural Research Studies FY 2005 New Format Data – 191 Studies

Race	Count	Percent of Total
White	818,226	88.0
Unknown/Not Reported	34,690	3.7
Black or African American	33,602	3.6
Asian	32,915	3.5
More Than One Race	7,009	0.8
American Indian/Alaska Native	3,254	0.4
Hawaiian/Pacific Islander	47	0.01
Total	929,743	100.0

**Intramural Research Studies
FY 2005 Accrual by Sex/Gender
367 Studies**

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	721,923	53.2	43.7
Male	631,500	46.5	56.3
Other/ Unknown	4,421	0.3	
Total	1,357,844	100.0	100.0

*US Cancer Incidence estimated from SEER Incidence Rates for 2000-2003 and US 2000 Census data.

CTEP Treatment Trials Cumulative Enrollment FY 1995–2006

N=3,359

Race/Ethnicity	Count	Percent of Total
White	262,817	83.1
Black or African American	26,499	8.4
Unknown	15,762	5.0
Asian	6,113	1.9
Not Reported	2,762	0.9
American Indian/Alaska Native	1,178	0.4
Native Hawaiian/Pacific Islander	916	0.3
More Than One Race	197	0.1
Total	316,244	100.0

**CTEP Treatment Trials
Cumulative Enrollment FY 1995–2006
by Gender**

N=3,359

Gender	Count	Percent of Total
Female	188,206	59.5
Male	121,755	38.5
Unknown	6,279	2.0
Not Reported	4	< 0.1
Total	316,244	100.0

CTEP Treatment Trials
Cumulative Enrollment FY 1995–2006 by Gender
(excluding Gender Specific Trials)

N=2,612

Sex/Gender	Count	Percent of Total
Female	70,262	40.6
Male	102,313	59.1
Unknown	402	0.2
Total	172,977	100.0

CTEP Treatment Trials FY 2005 Enrollment

N=967

Ethnicity	Count	Percent of Total
Not Hispanic or Latino	28,824	80.9
Unknown	4,270	13.4
Hispanic or Latino	1,657	5.2
Not Reported	166	0.5
Total	31,917	100.0

Race	Count	Percent of Total
White	27,186	85.2
Black or African American	2,441	7.6
Unknown	1,000	3.1
Asian	807	2.5
Not Reported	196	0.6
American Indian or Alaska Native	145	0.5
Native Hawaiian/Pacific Islander	84	0.3
More Than One Race	58	0.2
Total	31,917	100.0

CTEP Treatment Trials FY 2006 Enrollment

N=916

Ethnicity	Count	Percent of Total
Not Hispanic or Latino	26,720	81.2
Unknown	4,201	12.8
Hispanic or Latino	1,714	5.2
Not Reported	265	0.8
Total	32,900	100.0

Race	Count	Percent of Total
White	27,608	83.9
Black or African American	2,390	7.3
Unknown	1,597	4.9
Asian	768	2.3
Not Reported	272	0.8
American Indian or Alaska Native	140	0.4
Native Hawaiian/Pacific Islander	62	0.2
More Than One Race	63	0.2
Total	32,900	100.0

CTEP Treatment Trials FY 2005 and 2006 Enrollment by Gender

FY2005 (N=967)

Sex/Gender	Count	Percent of Total	U.S. Lifetime Cancer Prevalence*
Female	17,473	54.7	55.3
Male	11,803	37.0	44.7
Unknown	2,641	8.3	-
Total	31,917	100.0	100.0

FY2006 (N=916)

Sex/Gender	Count	Percent of Total	U.S. Lifetime Cancer Prevalence*
Female	19,176	62.0	55.3
Male	11,047	38.0	44.7
Unknown	2,677	8.1	-
Total	32,900	100.0	100.0

* SEER Data (Fast Stats), US estimated prevalence counts on 1/1/2003

CTEP Treatment Trials FY05 and 06 Enrollment by Gender (excluding Gender Specific Trials)

FY2005(N=762)

Sex/Gender	Count	Percent of Total	U.S. Lifetime Cancer Prevalence*
Female	7,191	41.3	55.3
Male	10,148	58.2	44.7
Unknown	85	0.5	-
Total	17,424	100.0	100.0

FY2006 (N=732)

Sex/Gender	Count	Percent of Total	U.S. Lifetime Cancer Prevalence*
Female	6,902	42.5	55.3
Male	9,265	57.1	44.7
Unknown	56	0.3	-
Total	16,223	100.0	100.0

* SEER Data (Fast Stats), US estimated prevalence counts on 1/1/2003.