

National Cancer Advisory Board

Biennial Review of Inclusion of Women and Minorities in Clinical Research

February 2009

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.”

- Reported 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

- ESAs 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 FY2007 and 2008, which represents subjects enrolled in FY2006 and 2007.

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 Cancer Incidence Rates*

	All Races/ Sexes	American Indian	Asian/ PI	Black	White	Hispanic
Rate per 100,000	467.4	312.7	313.5	500.6	475.3	357.6
Estimated New Cases 2001-2005	1,679,468	5,920	94,485	154,039	1,403,083	144,929
Estimated Percent		0.4	5.6	9.2	83.5	8.6

*US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

NCI Enrollment for FY 2007 and 2008 Extramural Research Studies by Sex/Gender

2007
2,713 Studies

Sex/Gender	Enrolled	Percent
Female	4,438,942	84.2
Male	803,435	15.2
Unknown	32,754	0.6
Total	5,273,131	100.0

2008
2,528 Studies

Sex/Gender	Enrolled	Percent
Female	4,346,250	82.1
Male	936,209	17.7
Unknown	9,859	0.2
Total	5,292,318	100.0

NCI Sex/Gender Enrollments FY 2007 and 2008 excluding All Male and All Female Studies

**2007 -1,949
Studies**

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	759,152	52.4	48.5
Male	658,055	45.4	51.5
Other/Unknown	32,754	2.3	
Total	1,449,961	100.0	100.0

**2008 -1,830
Studies**

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	886,271	54.7	48.5
Male	725,193	44.7	51.5
Other/Unknown	9,859	0.6	
Total	1,621,323	100.0	100.0

Subset of studies reported for 2007 and 2008; Studies include both Males and Females.

*US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

NCI Extramural Research Studies - Old Format

FY2007- 520 Studies FY2008 – 404 Studies

Race/ Ethnicity	2007 Number	2007 Percent	2008 Number	2008 Percent	US Cancer Incidence**
White	198,817	81.8	171,988	81.5	83.5
Black	18,342	7.6	16,068	7.6	9.2
Other	12,117	5.0	11,449	5.4	
Hispanic	8,705	3.6	7,279	3.5	(8.6)*
Asian/ Pacific Islander	4,079	1.7	3,641	1.7	5.6
American Indian/ Alaska Native	915	0.4	740	0.4	0.4
Total	242,975	100	211,165	100.0	100.00

*Percent Hispanic incidence included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

NCI Extramural Research Studies - New Format
FY2007 – 2,193 Studies **FY 2008 – 2,124 Studies**

Race/Ethnicity	2007 Count	2007 Percent	2008 Count	2008 Percent	US Cancer Incidence**
White	3,421,673	68.0	3,589,070	70.7	83.5
Unknown/Not Reported	569,889	11.3	555,139	10.9	
Asian	563,343	11.2	468,161	9.2	5.6
Black or African American	365,124	7.3	357,920	7.0	9.2
Hispanic or Latino*	(321,886)	(6.4)	(331,401)	(6.5)	(8.6)
American Indian/ Alaska Native	47,309	0.9	49,038	1.0	0.4
More Than One Race	44,004	0.9	44,465	0.9	
Native Hawaiian/ Pacific Islander	18,814	0.4	17,360	0.3	
Total	5,030,156	100.0	5,081,153	100.0	100.0

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

FY 2007 and 2008 NCI Enrollment Extramural Phase III Research Studies by Sex/Gender

FY 2007
250 Trials

Sex/Gender	Count	Percent of Total
Female	135,850	55.3
Male	109,632	44.7
Unknown	38	0.02
Total	245,520	100.0

FY 2008
329 Trials

Sex/Gender	Count	Percent of Total
Female	135,561	56.6
Male	103,992	43.4
Unknown	36	0.0
Total	239,589	100.0

NCI Enrollment Extramural Phase III Research Studies- Old Format

FY2007- 175 Studies FY2008 – 144 Studies

Race/Ethnicity	2007 Number	2007 Percent	2008 Number	2008 Percent	US Cancer Incidence*
White	140,821	82.2	128,739	82.6	83.5
Black	15,635	9.1	14,054	9.0	9.2
Hispanic	7,343	4.3	6,318	4.1	(8.6)
Unknown/Other	3,820	2.2	3,277	2.1	
Asian/Pacific Islander	3,114	1.8	2,856	1.8	5.6
American Indian/ Alaska Native	646	0.4	588	0.4	0.4
Total	171,379	100.0	155,832	100.0	100.0

*US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

NCI Extramural Phase III Research Studies - New Format

FY2007 – 163 Studies FY2008 – 185 Studies

Race/Ethnicity	2007 Count	2007 Percent	2008 Count	2008 Percent	US Cancer Incidence**
White	58,552	79.0	67,396	80.5	83.5
Asian	6,558	8.9	7,733	9.2	5.6
Black or African American	4,974	6.7	5,649	6.7	9.2
Hispanic or Latino*	(3,068)	(4.1)	(4,252)	(5.1)	(8.6)
Unknown/Not Reported	3,383	4.6	2,386	2.9	
Amer. Indian/Alaska Native	248	0.3	299	0.4	0.4
Hawaiian/Pacific Islander	131	0.2	147	0.2	
More Than One Race	295	0.4	147	0.2	
Total	74,141	100.0	83,757	100.0	100.0

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

NCI Intramural Research Studies – Old Format

FY 2007 – 90 Studies FY2008 - 78 Studies

Race/Ethnicity	2007 Number	2007 Percent	2008 Number	2008 Percent	US Cancer Incidence*
White	115,781	77.1	20,955	62.2	83.5
Black	24,920	16.6	10,680	31.7	9.2
Hispanic	4,620	3.1	947	2.8	(8.6)
Asian/Pacific Islander	3,232	2.2	687	2.0	5.6
Unknown/Other	1,327	0.1	403	1.2	
American Indian/Alaska Native	214	0.1	44	0.1	0.4
Total	150,094	100.0	33,716	100.0	100.0

*Percent Hispanic incidence included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

NCI Intramural Research Studies - New Format

FY 2007– 302 Studies FY 2008 – 356 Studies

Race/Ethnicity	2007 Count	2007 Percent	2008 Count	2008 Percent	US Cancer Incidence**
White	1,483,159	71.6	1,529,958	71.5	83.5
Unknown/Not Reported	203,659	9.8	219,053	10.2	
Black or African American	198,467	9.6	199,343	9.3	9.2
Asian	170,172	8.2	175,492	8.2	5.6
Hispanic or Latino*	(66,681)	(3.2)	(67,453)	(3.2)	(8.6)
More Than One Race	7,844	0.4	7,908	0.4	
American Indian/ Alaska Native	6,887	0.3	6,943	0.3	0.4
Hawaiian/Pacific Islander	1,662	0.1	1,853	0.1	
Total	2,071,850	100.0	2,140,550	100.0	100.0

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

Percentage of NCI Extramural and Intramural Enrollment

	FY 2007 %	FY 2008 %
Division of Cancer Control and Population Sciences	59.0	57.7
Division of Cancer Treatment and Diagnosis	6.4	10.4
Division of Cancer Prevention	2.7	2.4
Division of Cancer Biology	0.2	0.1
OD, Center to Reduce Cancer Health Disparities	0.7	0.1
Intramural	31.0	29.3
Total	100.0	100.0

CTEP Treatment Trials Enrollment

FY2007 – 3,189 Studies

FY2008 – 2,998 Studies

Race/Ethnicity	2007 Count	2007 Percent	2008 Count	2008 Percent	US Cancer Incidence**
White	25,475	84.4	24,780	83.3	83.5
Black or African American	2,404	8.0	2,468	8.3	9.2
Hispanic or Latino*	(1,981)	(6.6)	(2,029)	(6.8)	(8.6)
Unknown/ Not Reported	1,171	3.9	1,303	4.4	
Asian	861	2.9	957	3.2	5.6
American Indian/ Alaska Native	160	0.5	123	0.4	0.4
Native Hawaiian/ Pacific Islander	70	0.2	69	0.2	
More Than One Race	51	0.2	55	0.2	
Total	30,192	100.0	29,755	100.0	100.0

*Hispanic or Latino counts are not exclusive and may be included in other categories.

**US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

CTEP Treatment Trials Enrollment by Gender

FY2007 3,189 Studies	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
	Female	18,815	62.3	48.5
	Male	11,173	37.0	51.5
	Unknown	204	0.7	
	Total	30,192	100.0	100.0
FY2008 2,998 Studies	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
	Female	18,921	63.6	48.5
	Male	10,667	35.8	51.5
	Unknown	167	0.6	
	Total	29,755	100.0	100.0

*US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

CTEP Treatment Trials Enrollment by Gender (excluding Gender Specific Trials)

FY2007 2,504 Studies	Sex/Gender	2007 Count	Percent of Total	US Cancer Incidence*
	Female	6,510	41.6	48.5
	Male	9,088	58.1	51.5
	Unknown	50	0.3	
	Total	15,648	100.0	100.0
FY2008 2,355 Studies	Sex/Gender	2008 Count	Percent of Total	US Cancer Incidence*
	Female	6,292	41.7	48.5
	Male	8,744	57.9	51.5
	Unknown	66	0.4	
	Total	15,102	100.0	100.0

Subset of studies reported for 2007 and 2008; Studies include both Males and Females.

*US Cancer Incidence estimated from SEER Incidence Rates for 2001-2005 and US 2000 Census data.

NCI Population Tracking Accrual Working Group

- Division of Extramural Activities
 - Gail Blaufarb, Chair
 - Clarissa Douglas
- Division of Cancer Biology
 - Jennifer Strasburger
- Division of Cancer Control and Population Sciences
 - Mark Alexander
 - Yvonne Grant
- Division of Cancer Prevention
 - Cynthia Whitman
- Division of Cancer Treatment and Diagnosis
 - Elise Kreiss
 - Kim Witherspoon
 - Peter Ujhazy
- Office of Centers, Training, and Resources
 - Jaswant Bhorjee
 - Tarsha McCrae