

National Cancer Advisory Board

Biennial Review of Inclusion of Women and Minorities in Clinical Research

February 2011

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 Extramural Research and includes a 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 FY2009 and 2010, which represents subjects enrolled in FY2008 and 2009.

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 for All Cancers 2003-2007

	White	Black	Asian/ PI	American Indian	Total (All Races/ Sexes)	Hispanic **
Incidence Rate per 100,000	469.2	489.8	310.8	317.7	461.6	342.5
Reported New Cases	1,424,834	158,072	101,708	6,485	1,717,500	153,583
Estimated Percent of Total*	83.0	9.2	5.9	0.4	100	8.9

*US Cancer Percent estimated from SEER Reported New Cases for 2003-2007.

**Hispanic incidence included in other categories.

NCI Enrollment for FY 2009 and 2010 Extramural Research Studies by Sex/Gender

2009
3,032 Studies

Sex/Gender	Enrolled	Percent
Female	4,786,715	82.3
Male	1,015,393	17.5
Unknown	12,919	0.2
Total	5,815,027	100

2010
2,706 Studies

Sex/Gender	Enrolled	Percent
Female	4,155,672	69.7
Male	1,794,593	30.1
Unknown	12,140	0.2
Total	5,962,405	100

NCI Sex/Gender Enrollments FY 2009 and 2010 excluding All Male and All Female Studies

**2009 -2,177
Studies**

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	828,593	52.7	48.5
Male	729,607	46.4	51.5
Other/Unknown	12,919	0.8	
Total	1,571,119	100	100

**2010 -1,950
Studies**

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	636,221	52.1	48.5
Male	571,881	46.9	51.5
Other/Unknown	12,140	1.0	
Total	1,220,242	100	100

Subset of studies reported for 2009 and 2010; Studies include both Males and Females.

*US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

NCI Extramural Research Studies - Old Format

FY2009- 410 Studies FY2010 – 132 Studies

Race/ Ethnicity	2009 Number	2009 Percent	2010 Number	2010 Percent	US Cancer Incidence**
White	163,963	81.4	68,982	84.2	83.0
Black	14,498	7.2	7,077	8.6	9.2
Other	12,439	6.2	851	1.0	
Hispanic	6,299	3.1	3,397	4.1	(8.9)*
Asian/ Pacific Islander	3,635	1.8	1,274	1.6	5.9
American Indian/ Alaska Native	691	0.3	311	0.4	0.4
Total	201,525	100	81,892	100	100

*Percent Hispanic incidence included in other categories.

**US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

NCI Extramural Research Studies - New Format

FY2009 – 2,622 Studies **FY 2010 – 2,574 Studies**

Race/Ethnicity	2009 Count	2009 Percent	2010 Count	2010 Percent	US Cancer Incidence**
White	3,800,173	67.7	3,980,947	67.7	83.0
Asian	851,773	15.2	818,180	13.9	5.9
Unknown/Not Reported	541,128	9.6	532,162	9.0	
Black or African American	315,535	5.6	435,338	7.4	9.2
Hispanic or Latino*	(320,665)	(5.7)	(354,381)	(6.0)	(8.9)
American Indian/ Alaska Native	45,552	0.8	48,239	0.8	0.4
More Than One Race	42,116	0.8	46,159	0.8	
Native Hawaiian/ Pacific Islander	17,225	0.3	19,488	0.3	
Total	5,613,502	100	5,880,513	100	100

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

**US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

FY 2009 and 2010 NCI Enrollment Extramural Phase III Research Studies by Sex/Gender

FY 2009
466 Trials

Sex/Gender	Count	Percent of Total
Female	174,106	57.9
Male	125,827	41.8
Unknown	851	0.3
Total	300,784	100
Sex/Gender	Count	Percent of Total
Female	125,484	54.1
Male	106,556	45.9
Unknown	33	0.0
Total	232,073	100

FY 2010
368 Trials

NCI Enrollment Extramural Phase III Research Studies- Old Format

FY2009- 181 Studies FY2010 – 51 Studies

Race/Ethnicity	2009 Number	2009 Percent	2010 Number	2010 Percent	US Cancer Incidence*
White	130,668	83.0	63,423	84.1	83.0
Black	13,318	8.5	6,658	8.8	9.2
Hispanic	5,763	3.7	3,149	4.2	(8.9)
Unknown/Other	4,021	2.6	726	1.0	
Asian/Pacific Islander	3,018	1.9	1,129	1.5	5.9
American Indian/ Alaska Native	578	0.4	291	0.4	0.4
Total	157,366	100	75,376	100	100

*US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

NCI Extramural Phase III Research Studies - New Format

FY2009 – 285 Studies

FY2010 – 317 Studies

Race/Ethnicity	2009 Count	2009 Percent	2010 Count	2010 Percent	US Cancer Incidence**
White	118,882	82.9	128,229	81.8	83.0
Asian	9,581	6.7	11,144	7.1	5.9
Black or African American	9,814	6.8	10,857	6.9	9.2
Hispanic or Latino*	(7,296)	(5.1)	(8,690)	(5.5)	(8.9)
Unknown/Not Reported	4,071	2.8	5,274	3.4	
Amer. Indian/Alaska Native	517	0.4	575	0.4	0.4
Hawaiian/Pacific Islander	238	0.2	279	0.2	
More Than One Race	315	0.2	339	0.2	
Total	143,418	100	156,697	100	100

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

**US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

NCI Intramural Research Studies – Old Format

FY 2009 – 73 Studies

FY2010 - 70 Studies

Race/Ethnicity	2009 Number	2009 Percent	2010 Number	2010 Percent	US Cancer Incidence **
White	21,788	81.4	23,570	81.2	83.0
Black	2,679	10.0	2,957	10.2	9.2
Hispanic	1,171	4.4	1,187	4.1	(8.9)*
Asian/Pacific Islander	727	2.7	826	2.9	5.9
Unknown/Other	356	1.3	420	1.2	
American Indian/Alaska Native	44	0.2	52	0.2	0.4
Total	26,765	100	29,012	100	100

*Percent Hispanic incidence included in other categories.

**US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

NCI Intramural Research Studies - New Format

FY 2009– 387 Studies

FY 2010 – 434 Studies

Race/Ethnicity	2009 Count	2009 Percent	2010 Count	2010 Percent	US Cancer Incidence**
White	1,481,220	70.0	1,507,538	69.8	83.0
Unknown/Not Reported	228,775	10.1	249,295	11.5	
Black or African American	201,560	9.6	210,858	9.8	9.2
Asian	181,267	8.6	184,793	8.6	5.9
Hispanic or Latino*	(66,726)	(3.2)	(68,173)	(3.2)	(8.9)
American Indian/ Alaska Native	6,009	0.3	6,262	0.3	0.4
More Than One Race	2,925	0.1	1,409	0.1	
Hawaiian/Pacific Islander	949	0.1	1,034	0.1	
Total	2,102,715	100	2,161,189	100	100

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

**US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

Percentage of NCI Extramural and Intramural Enrollment

	FY 2009 %	FY 2010 %
Division of Cancer Control and Population Sciences	58.8	64.4
Division of Cancer Treatment and Diagnosis	11.6	5.7*
Division of Cancer Prevention	2.4	3.0
Division of Cancer Biology	0.1	0.1
OD, Center to Reduce Cancer Health Disparities	0.2	0.1
Intramural	26.9	26.7
Total	100	100

*FY 2010 DCTD data are incomplete. The first three quarters of the year are reported.

CTEP Treatment Trials Enrollment

FY2009 – 610 Studies

FY2010 – 527 Studies

Race/Ethnicity	2009 Count	2009 Percent	2010* Count	2010* Percent	US Cancer Incidence***
White	26,922	83.7	16,965	82.5	83.0
Black or African American	2,586	8.0	1,755	8.5	9.2
Hispanic or Latino**	(2,394)	(7.4)	(1,672)	(8.1)	(8.9)
Unknown/ Not Reported	1,273	4.0	927	4.5	
Asian	1,080	3.4	722	3.5	5.9
American Indian/ Alaska Native	138	0.4	104	0.5	0.4
Native Hawaiian/ Pacific Islander	92	0.3	62	0.3	
More Than One Race	66	0.2	29	0.1	
Total	32,157	100	20,564*	100*	100

*FY 2010 data are incomplete. The first three quarters of the year are reported.

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

***US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

CTEP Treatment Trials Enrollment by Gender

FY2009
610 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	21,911	68.1	48.5
Male	10,234	31.8	51.5
Unknown	12	0.1	
Total	32,157	100	100

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	13,251	64.4	48.5
Male	7,308	35.5	51.5
Unknown	5	0.1	
Total	20,564**	100**	100

FY2010**
527 Studies

*US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

**FY 2010 data are incomplete. The first three quarters of the year are reported.

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

FY2009
488 Studies

Sex/Gender	2009 Count	Percent of Total	US Cancer Incidence*
Female	6,259	43.2	48.5
Male	8,238	56.8	51.5
Unknown	5	0.0	
Total	14,502	100	100

FY2010**
413 Studies

Sex/Gender	2010 Count	Percent of Total	US Cancer Incidence*
Female	4,587	42.9	48.5
Male	6,101	57.1	51.5
Unknown	4	0.0	
Total	10,692**	100**	100

Subset of studies reported for 2009 and 2010; Studies include both Males and Females.

* US Cancer Incidence estimated from SEER Reported New Cases for 2003-2007.

**FY 2010 data are incomplete. The first three quarters of the year are reported.

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
- Division of Cancer Prevention
 - Cynthia Whitman
- Division of Cancer Treatment and Diagnosis
 - Rolanda Wade-Ricks
 - Kim Witherspoon
 - Peter Ujhazy
- Office of Centers, Training, and Resources
 - Jaswant Bhorjee
 - Martha Hare