

National Cancer Advisory Board

Biennial Review of Inclusion of Women and Minorities in Clinical Research

February 2013

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 clinical trials whether treatment, behavioral, or epidemiologic observation.
 - Individual clinical trials vary considerably.
 - Large population-based screening trials dominate aggregate data.

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 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 FY2011 and 2012, which represents subjects enrolled in FY2010 and 2011.

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 2005-2009

	White	Black	Asian/ PI	American Indian	Total (All Races/ Sexes)	Hispanic **
Incidence Rate per 100,000	471.7	489.5	315.0	328.9	465.2	353.7
Number of Incidence Cases	1,577,573	194,295	111,376	7,255	1,922,239	175,955
Estimated Percent of Total*	82.1%	10.1%	5.8%	0.4%	100%	9.2%

*US Cancer Percent estimated from SEER Number of Incidence Cases for 2005-2009.

**Hispanic incidence included in other categories.

NCI Enrollment for FY 2011 and 2012 Extramural Research Studies by Sex/Gender

**2011
2,392 Studies**

Sex/Gender	Enrolled	Percent	US Cancer Incidence*
Female	4,279,066	70.5%	48.4%
Male	1,758,184	29.0%	51.6%
Unknown	28,225	0.5%	
Total	6,065,475	100%	100%

**2012
2,169 Studies**

Sex/Gender	Enrolled	Percent	US Cancer Incidence*
Female	3,359,328	53.9%	48.4%
Male	2,858,916	45.8%	51.6%
Unknown	19,620	0.3%	
Total	6,237,864	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009

NCI Sex/Gender Enrollments FY 2011 and 2012 excluding All Male and All Female Studies

**2011 -1,695
Studies**

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	693,041	50.3%	48.4%
Male	655,652	47.6%	51.6%
Other/Unknown	28,225	2.1%	
Total	1,376,918	100%	100%

**2012 -1,561
Studies**

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	2,109,101	52.9%	48.4%
Male	1,859,443	46.6%	51.6%
Other/Unknown	19,620	0.5%	
Total	3,988,164	100%	100%

Subset of studies reported for 2011 and 2012; Studies include both Males and Females.

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

NCI Extramural Research Studies

FY 2011 – 2,392 Studies

FY 2012 – 2,169 Studies

Race/Ethnicity	2011 Count	2011 Percent	2012 Count	2012 Percent	US Cancer Incidence**
White	4,123,883	68.0%	3,772,476	60.5%	82.1%
Asian	817,196	13.5%	591,279	9.5%	5.8%
Unknown/Not Reported	545,393	9.0%	1,237,091	19.8%	
Black or African American	452,198	7.5%	537,974	8.6%	10.1%
Hispanic or Latino*	(391,220)	(6.5%)	(549,827)	(8.8%)	(9.2%)
American Indian/ Alaska Native	49,849	0.8%	24,502	0.4%	0.4%
More Than One Race	58,375	1.0%	45,994	0.7%	
Native Hawaiian/ Pacific Islander	18,581	0.3%	28,548	0.5%	
Total	6,065,475	100%	6,237,864	100%	100%

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

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

FY 2011 and 2012 NCI Enrollment Extramural Phase III Research Studies by Sex/Gender

		Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2011 306 Trials		Female	86,317	58.3%	48.4%
		Male	61,718	41.7%	51.6%
		Unknown	50	0.03%	
		Total	148,085	100%	100%
		Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2012 267 Trials		Female	67,312	58.1%	48.4%
		Male	48,312	41.7%	51.6%
		Unknown	159	0.1%	
		Total	115,783	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

NCI Extramural Phase III Research Studies

FY 2011 – 306 Studies

FY 2012 – 267 Studies

Race/Ethnicity	2011 Count	2011 Percent	2012 Count	2012 Percent	US Cancer Incidence**
White	118,896	80.2%	87,661	75.7%	82.1%
Asian	11,311	7.6%	9,490	8.1%	5.8%
Black or African American	11,103	7.5%	12,761	11.0%	10.1%
Hispanic or Latino*	(9,261)	(6.3%)	(7,381)	(6.4%)	(9.2%)
Unknown/Not Reported	5,465	3.7%	4,569	3.9%	
Amer. Indian/Alaska Native	623	0.4%	516	0.4%	0.4%
Hawaiian/Pacific Islander	359	0.2%	270	0.2%	
More Than One Race	328	0.2%	516	0.4%	
Total	148,085	100%	115,783	100%	100%

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

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

NCI Intramural Research Studies

FY 2011– 522 Studies

FY 2012 – 565 Studies

Race/Ethnicity	2011 Count	2011 Percent	2012 Count	2012 Percent	US Cancer Incidence**
White	1,543,245	69.4%	1,653,693	45.6%	82.1%
Unknown/Not Reported	262,438	11.8%	1,510,138	41.6%	
Black or African American	212,682	9.6%	243,094	6.7%	10.1%
Asian	195,464	8.8%	205,930	5.7%	5.8%
Hispanic or Latino*	(78,129)	(3.5%)	(110,638)	(3.1%)	(9.2%)
American Indian/ Alaska Native	6,339	0.3%	7,018	0.2%	0.4%
More Than One Race	1,582	0.1%	4,102	0.1%	
Hawaiian/Pacific Islander	1,096	0.1%	2,083	0.1%	
Total	2,222,846	100%	3,626,058	100%	100%

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

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

CTEP Treatment Trials Enrollment

FY 2011 – 596 Studies

FY 2012 – 541 Studies

Race/Ethnicity	2011 Count	2011 Percent	2012 Count	2012 Percent	US Cancer Incidence**
White	19,020	81.1%	19,663	81.8%	82.1%
Black or African American	2,217	9.5%	2,157	8.9%	10.1%
Hispanic or Latino*	(1,844)	(7.9%)	(1,920)	(8.0%)	(9.2%)
Unknown/ Not Reported	1,092	4.7%	1,066	4.4%	
Asian	852	3.6%	887	3.0%	5.8%
American Indian/ Alaska Native	114	0.5%	124	0.5%	0.4%
Native Hawaiian/ Pacific Islander	81	0.3%	78	0.3%	
More Than One Race	53	0.2%	59	0.2%	
Total	23,429	100%	24,034	100%	100%

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

**US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

CTEP Treatment Trials Enrollment by Gender

FY 2011
596 Studies

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	14,103	60.2%	48.4%
Male	9,303	39.7%	51.6%
Unknown	23	0.1%	
Total	23,429	100%	100%

Sex/Gender	Count	Percent of Total	US Cancer Incidence*
Female	14,321	59.6%	48.4%
Male	9,696	40.3%	51.6%
Unknown	17	0.1%	
Total	24,034	100%	100%

FY 2012
541 Studies

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

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

**FY 2011
459 Studies**

Sex/Gender	2011 Count	Percent of Total	US Cancer Incidence*
Female	7,551	48.7%	48.4%
Male	7,928	51.1%	51.6%
Unknown	23	0.2%	
Total	15,502	100%	100%

Sex/Gender	2012 Count	Percent of Total	US Cancer Incidence*
Female	7,819	48.8%	48.4%
Male	8,184	51.1%	51.6%
Unknown	17	0.1%	
Total	16,020	100%	100%

**FY 2012
406 Studies**

Subset of studies reported for 2011 and 2012; Studies include both Males and Females.

* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

DCP Trials Enrollment

2011 – 63 Studies

2012 – 70 Studies

Race/Ethnicity	2011 Count	2011 Percent	2012 Count	2012 Percent	US Cancer Incidence*
White	5,503	83.3%	8,514	85.2%	82.1%
Black or African American	664	10.1%	939	9.4%	10.1%
Hispanic or Latino*	(350)	(5.3%)	(454)	(4.5%)	(9.2%)
Asian	196	2.8%	246	2.5%	5.8%
Unknown/ Not Reported	165	2.6%	198	2.0%	
American Indian/ Alaska Native	52	0.8%	62	0.6%	0.4%
Native Hawaiian/ Pacific Islander	17	0.3%	14	0.1%	
More Than One Race	8	0.1%	21	0.2%	
Total	6,605	100%	9,994	100%	100%

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

** US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

DCP Trials Enrollment by Gender

		Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2011	63 Studies	Female	4,553	68.9%	48.4%
		Male	2,019	30.6%	51.6%
		Unknown	33	0.5%	
		Total	6,605	100%	100%
		Sex/Gender	Count	Percent of Total	US Cancer Incidence*
FY 2012	70 Studies	Female	6,036	60.4%	48.4%
		Male	3,938	39.4%	51.6%
		Unknown	20	0.2%	
		Total	9,994	100%	100%

* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

DCP Trials Enrollment by Gender (excluding Gender Specific Trials)

FY 2011 45 Studies	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
	Female	2,784	58.1%	48.4%
	Male	1,971	41.2%	51.6%
	Unknown	33	0.7%	
	Total	4,788	100%	100%
FY 2012 44 Studies	Sex/Gender	Count	Percent of Total	US Cancer Incidence*
	Female	3,068	44.8%	48.4%
	Male	3,761	54.9%	51.6%
	Unknown	20	0.3%	
	Total	6,849	100%	100%

Subset of studies reported for 2011 and 2012; Studies include both Males and Females.

* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2005-2009.

NCI Population Tracking Accrual Working Group

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