

National Cancer Advisory Board

Triennial Review of Inclusion of Women and Minorities in Clinical Research

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.

21st Century Cures Act, P.L. 114-255,
Section 2032. Triennial Reports enacted
December 13, 2016

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

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

- *Program Officials 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 Officials.*
- *Target and enrollment numbers are entered into the NIH Inclusion Monitoring System (IMS).*
- *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 FY2016, 2017 and 2018.

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 2011 - 2015

	White	Black	Asian/PI	American Indian	Total (All Races/ Sexes)	Hispanic**
Incidence Rate per 100,000*	448.8	453.4	297.9	315.1	439.2	336.3
Number of Incidence Cases	1,676,377	223,392	140,689	9,149	2,087,262	220,990
Estimated Percent of Total*	80.3%	10.7%	6.7%	0.4%	100%	10.6%

*US Cancer Percent estimated from SEER Number of Incidence Cases for 2011-2015.

**Hispanic incidence included in other categories.

NCI Enrollment for FY 2016, 2017 and 2018 Extramural Research Studies by Sex/Gender

2016
1,844 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	1,784,727	66.9%	49.8%
Male	873,126	32.7%	50.2%
Unknown	8,219	0.3%	
Total	2,666,072	100%	100%

2017
1,893 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	1,080,692	57.6%	49.8%
Male	718,833	38.4%	50.2%
Unknown	75,615	4.0%	
Total	1,875,140	100%	100%

2018
2,379 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	1,076,639	64.7%	49.8%
Male	420,449	25.3%	50.2%
Unknown	166,991	10.0%	
Total	1,664,079	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

NCI Extramural Research Studies by Race/Ethnicity

FY 2016 – 1,844 Studies
FY 2017 – 1,893 Studies
FY 2018 – 2,379 Studies

Race/Ethnicity	2016 Count	2016 Percent	2017 Count	2017 Percent	2018 Count	2018 Percent	US Cancer Incidence**
White	2,292,056	86.0%	1,478,501	78.8%	1,039,837	62.5 %	80.3%
Asian	76,968	2.9%	45,626	2.4%	86,104	5.2%	6.7%
Black or African American	173,002	6.5%	130,870	7.0%	168,651	10.1%	10.7%
Hispanic or Latino*	(221,866)	(8.3%)	(181,440)	(9.7%)	158,186	(9.5%)	(10.6%)
Unknown/Not Reported	78,190	2.9%	171,809	9.2%	315,934	19.0%	-
More Than One Race	31,937	1.2%	36,010	1.9%	40,917	2.5%	-
Native Hawaiian/ Pacific Islander	4,728	0.2%	3,168	0.2%	2,981	0.2%	-
American Indian/ Alaska Native	9,191	0.3%	9,156	0.5%	9,655	0.6%	0.4%
Total	2,666,072	100%	1,875,140	100%	1,664,079	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 2011-2015.

**NCI Extramural Sex/Gender Enrollments FY 2016, 2017 and 2018
excluding All Male and All Female Studies**

2016
1,515 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	762,587	49.7%	49.8%
Male	764,645	49.8%	50.2%
Unknown	8,219	0.5%	
Total	1,535,451	100.0%	100%

2017
1532 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	573,977	45.5%	49.8%
Male	613,151	48.6%	50.2%
Unknown	75,615	6.0%	
Total	1,262,743	100.0%	100%

2018
1682 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	314,428	40.1%	49.8%
Male	303,311	38.7%	50.2%
Unknown	166,991	21.3%	
Total	784,730	100.0%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

NCI Extramural Phase III Research Studies by Sex/Gender

2016
130 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	35,946	54.7	49.8%
Male	29,648	45.2	50.2%
Unknown	69	0.1	
Total	65,663	100%	100%

2017
144 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	41,187	54.2%	49.8%
Male	34,673	45.7%	50.2%
Unknown	70	0.1%	
Total	75,930	100%	100%

2018
201 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	71,733	60.4	49.8%
Male	46,964	39.5	50.2%
Unknown	74	0.1	
Total	118,771	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

NCI Extramural Phase III Research Studies by Race/Ethnicity

FY 2016 – 130 Studies FY 2017 – 144 Studies FY2018 – 201 Studies

Race/Ethnicity	2016 Count	2016 Percent	2017 Count	2017 Percent	2018 Count	2018 Percent	US Cancer Incidence**
White	52,406	79.8%	60,853	80.1%	87,698	73.8%	80.3%
Asian	2,878	4.4%	2,319	3.1%	3,277	2.8%	6.7%
Black or African American	6,692	10.2%	8,205	10.8%	12,150	10.2%	10.7%
Hispanic or Latino*	(6,650)	(10.1%)	(8,194)	(10.8%)	(11,864)	(10.0)	(10.6%)
Unknown/Not Reported	3,063	4.7%	3,787	5.0%	5,341	4.5%	-
More Than One Race	170	0.3%	152	0.2%	9,375	7.9%	-
Native Hawaiian/ Pacific Islander	100	0.2%	190	0.3%	316	0.3%	-
American Indian/ Alaska Native	354	0.5%	424	0.6%	614	0.5%	0.4%
Total	65,663	100%	75,930	100%	118,771	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 2011-2015.

NCI Intramural Research Studies by Race/Ethnicity

FY 2016 – 524 Studies FY 2017 – 539 Studies FY2018 – 504 Studies

Race/Ethnicity	2016 Count	2016 Percent	2017 Count	2017 Percent	2018 Count	2018 Percent	US Cancer Incidence**
White	1,068,908	42.4%	1,092,549	81.3%	985,807	86.4%	80.3%
Asian	25,054	1.0%	25,654	1.9%	12,968	1.1%	6.7%
Black or African American	89,608	3.6%	94,479	7.0%	50,612	4.4%	10.7%
Hispanic or Latino*	(60,660)	(2.4%)	(61,915)	(4.6%)	23,149	(2.0%)	(10.6%)
Unknown/Not Reported	1,329,573	52.7%	122,725	9.1%	84,103	7.4%	-
More Than One Race	2,389	0.1%	2,298	0.2%	2,897	0.3%	-
Native Hawaiian/ Pacific Islander	2,022	0.1%	2,053	0.2%	870	0.1%	-
American Indian/ Alaska Native	4,568	0.2%	4,611	0.3%	3,910	0.3%	0.4%
Total	2,522,122	100%	1,344,369	100%	1,141,167	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 2011-2015.

CTEP Treatment Trials by Race/Ethnicity

FY2016 – 323 Studies FY2017 – 298 Studies FY2018 – 281 Studies

Race/Ethnicity	2016 Count	2016 Percent	2017 Count	2017 Percent	2018 Count	2018 Percent	US Cancer Incidence**
White	14,153	75.0%	15,147	73.0%	11,491	73.0%	80.3%
Asian	734	4.0%	826	4.0%	613	4.0%	6.7%
Black or African American	2,088	11.0%	2,657	13.0%	2,316	15.0%	10.7%
Hispanic or Latino*	1,956	10.0%	2,154	10.0%	1,952	12.0%	(10.6%)
Unknown/Not Reported	1,598	8.0%	1,773	9.0%	1,042	7.0%	-
More Than One Race	137	1.0%	142	1.0%	155	1.0%	-
Native Hawaiian/ Pacific Islander	58	0%	86	0%	52	0%	-
American Indian/ Alaska Native	111	1.0%	134	1.0%	80	1.0%	0.4%
Total	18,879	100%	20,765	100%	15,749	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 2011-2015.

CTEP Treatment Trials Enrollment by Gender

FY2016
323 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	9,039	48.0%	49.8%
Male	9,840	52.0%	50.2%
Unknown	0	0%	-
Total	18,879	100%	100%

FY2017
298 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	11,509	55.0%	49.8%
Male	9,254	45.0%	50.2%
Unknown	2	0%	-
Total	20,765	100%	100%

FY2018
281 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	8,226	52.0%	49.8%
Male	7,523	48.0%	50.2%
Unknown	0	0%	-
Total	15,749	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

CTEP Treatment Trials Enrollment by Gender excluding Gender Specific Trials

FY2016
280 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	7,175	46.0%	49.8%
Male	8,320	54.0%	50.2%
Unknown	0	0%	-
Total	15,495	100%	100%

FY2017
260 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	8,319	49.0%	49.8%
Male	8,552	51.0%	50.2%
Unknown	2	0%	-
Total	16,873	100%	100%

FY2018
250 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	6,049	48.0%	49.8%
Male	6,477	52.0%	50.2%
Unknown	0	0%	-
Total	12,526	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

DCP Trials by Race/Ethnicity

FY2016 – 165 Studies

FY2017 – 214 Studies

FY2018 – 245 Studies

Race/Ethnicity	2016 Count	2016 Percent	2017 Count	2017 Percent	2018 Count	2018 Percent	US Cancer Incidence**
White	27,958	75.1%	52,150	82.0%	44,510	79.1%	80.3%
Asian	1,809	4.9%	2,246	3.5%	2,902	5.2%	6.7%
Black or African American	4,089	11.0%	4,626	7.3%	5,500	9.8%	10.7%
Hispanic or Latino*	5,301	(14.2%)	(26,063)	(41.0%)	(4,720)	(8.4%)	(10.6%)
Unknown/Not Reported	2,700	7.2%	2,698	4.2%	2,017	3.6%	-
More Than One Race	359	1.0%	1,422	2.2%	563	1.0%	-
Native Hawaiian/ Pacific Islander	81	0.2%	177	0.3%	258	0.5%	-
American Indian/ Alaska Native	255	0.7%	247	0.4%	532	0.9%	0.4%
Total	37,251	100.0%	63,566	100%	56,282	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 2011-2015.

DCP Trials Enrollment by Gender

FY 2016
165 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	25,532	68.5%	49.8%
Male	11,681	31.4%	50.2%
Unknown	38	0.1%	-
Total	37,251	100%	100%

FY 2017
214 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	49,788	78.3%	49.8%
Male	13,496	21.2%	50.2%
Unknown	282	0.4%	-
Total	63,566	100%	100%

FY 2018
245 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	37,094	65.9%	49.8%
Male	18,735	33.3%	50.2%
Unknown	453	0.8%	-
Total	56,282	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

DCP Trials Enrollment by Gender excluding Gender Specific Trials

FY 2016
82 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	13,462	58.1%	49.8%
Male	9,659	41.7%	50.2%
Unknown	38	0.2%	-
Total	23,159	100%	100%

FY 2017
111 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	16,879	58.4%	49.8%
Male	11,729	40.6%	50.2%
Unknown	282	1.0%	-
Total	28,890	100%	100%

FY 2018
164 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	20,229	54.0%	49.8%
Male	16,793	44.8%	50.2%
Unknown	453	1.2%	-
Total	37,475	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

DCCPS Epidemiology Trials Enrollment by Gender

FY 2016
300 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	2,968,486	45.7%	49.8%
Male	3,517,536	54.2%	50.2%
Unknown	2,744	0.4%	-
Total	6,488,766	100%	100%

FY 2017
336 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	2,311,645	40.0%	49.8%
Male	3,402,486	58.8%	50.2%
Unknown	71,797	1.2%	-
Total	5,785,928	100%	100%

FY 2018
261 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	776,802	71.5%	49.8%
Male	149,133	13.7%	50.2%
Unknown	160,808	14.8%	-
Total	1,086,743	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

DCCPS Epidemiology Trials Enrollment by Gender excluding Gender Specific Trials

FY 2016
204 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	2,272,922	39.6%	49.8%
Male	3,457,339	60.3%	50.2%
Unknown	2,744	0.05%	-
Total	5,733,005	100%	100%

FY 2017
243 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	2,099,306	38.1%	49.8%
Male	3,339,989	60.6%	50.2%
Unknown	71,797	1.3%	-
Total	5,511,092	100%	100%

FY 2018
196 Studies

Sex/Gender	Enrolled	Percent of Total	U.S. Cancer Incidence*
Female	87,807	26.9%	49.8%
Male	77,392	23.7%	50.2%
Unknown	160,808	49.3%	-
Total	326,007	100%	100%

*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2011-2015.

DCCPS Epidemiology Trials by Race/Ethnicity

FY 2016 – 300 Studies FY 2017 – 336 Studies FY 2018 – 261 Studies

Race/Ethnicity	2016 Count	2016 Percent	2017 Count	2017 Percent	2018 Count	2018 Percent	US Cancer Incidence**
White	1,526,269	23.5%	786,886	13.6%	595,498	54.8%	80.3%
Asian	56,940	0.9%	4,766,712	82.4%	68,573	6.3%	6.7%
Black or African American	110,283	1.7%	73,725	1.3%	116,655	10.7%	10.7%
Hispanic or Latino*	(97,771)	(1.5%)	(87,796)	(1.5%)	(58,289)	(5.4%)	(10.6%)
Unknown/Not Reported	4,771,691	73.5%	130,216	2.3%	281,191	25.9%	-
More Than One Race	13,672	0.2%	20,130	0.3%	16,440	1.5%	-
Native Hawaiian/ Pacific Islander	3,933	0.1%	2,208	0.04%	1,992	0.2%	-
American Indian/ Alaska Native	5,978	0.1%	6,051	0.1%	6,394	0.6%	0.4%
Total	6,488,766	100%	5,785,928	100%	1,086,743	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 2011-2015.

NCI Accrual Working Group

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