

# National Cancer Advisory Board

## Biennial Review of Inclusion of Women and Minorities in Clinical Research

February 2015

# 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 FY2013 and 2014, which represents subjects enrolled in FY2012 and 2013.

# 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 Incidence for All Cancers 2007-2011

	White	Black	Asian/ PI	American Indian	Total (All Races/ Sexes)	Hispanic **
<b>Incidence Rate per 100,000*</b>	<b>468.9</b>	<b>480.8</b>	<b>306.7</b>	<b>319.3</b>	<b>460.4</b>	<b>353.2</b>
<b>Number of Incidence Cases</b>	<b>1,628,476</b>	<b>208,379</b>	<b>121,493</b>	<b>7,934</b>	<b>2,001,481</b>	<b>190,832</b>
<b>Estimated Percent of Total*</b>	<b>81.4%</b>	<b>10.4%</b>	<b>6.1%</b>	<b>0.4%</b>	<b>100%</b>	<b>9.5%</b>

\*US Cancer Percent estimated from SEER Number of Incidence Cases for 2007-2011.

\*\*Hispanic incidence included in other categories.

# NCI Enrollment for FY 2013 and 2014 Extramural Research Studies by Sex/Gender

**2013**  
**2,033 Studies**

<b>Sex/Gender</b>	<b>Enrolled</b>	<b>Percent</b>	<b>US Cancer Incidence*</b>
<b>Female</b>	<b>2,677,294</b>	<b>56.34%</b>	<b>48.3%</b>
<b>Male</b>	<b>2,067,444</b>	<b>43.51%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>7,156</b>	<b>0.15%</b>	
<b>Total</b>	<b>4,751,894</b>	<b>100%</b>	<b>100%</b>

**2014**  
**1837 Studies**

<b>Sex/Gender</b>	<b>Enrolled</b>	<b>Percent</b>	<b>US Cancer Incidence*</b>
<b>Female</b>	<b>3,017,336</b>	<b>68.6%</b>	<b>48.3%</b>
<b>Male</b>	<b>1,151,814</b>	<b>26.2%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>229,040</b>	<b>5.2%</b>	
<b>Total</b>	<b>4,398,190</b>	<b>100%</b>	<b>100%</b>

\*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011

# NCI Sex/Gender Enrollments FY 2013 and 2014 excluding All Male and All Female Studies

## 2013 -1424 Studies

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	1,435,030	57.8%	48.3%
Male	1,041,138	41.9%	51.7%
Other/Unknown	7,156	0.3%	
<b>Total</b>	<b>2,483,324</b>	<b>100%</b>	<b>100%</b>

## 2014 -1318 Studies

Sex/ Gender	Enrollment	Percent of Total	US Cancer Incidence*
Female	1,431,549	56.0%	48.3%
Male	881,103	35.0%	51.7%
Other/Unknown	229,040	9.0%	
<b>Total</b>	<b>2,541,692</b>	<b>100%</b>	<b>100%</b>

Subset of studies reported for 2013 and 2014; Studies include both Males and Females.

\*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

# NCI Extramural Research Studies by Race/Ethnicity

FY 2013 – 2,033 Studies
FY 2014 – 1,837 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	3,240,056	68.18%	2,950,325	67.08%	81.4%
Asian	562,949	11.85%	567,709	12.91%	6.1%
Black or African American	480,777	10.12%	435,433	9.90%	10.4%
Hispanic or Latino*	(380,587)	(8.01%)	(314,478)	(7.15%)	(9.5%)
Unknown/Not Reported	380,562	8.0%	350,291	7.96%	
More Than One Race	49,410	1.04%	54,120	1.23%	
Native Hawaiian/ Pacific Islander	20,413	0.43%	22,330	0.51%	
American Indian/ Alaska Native	17,727	0.37%	17,982	0.41%	0.4%
<b>Total</b>	<b>4,751,894</b>	<b>100%</b>	<b>4,398,190</b>	<b>100%</b>	<b>100%</b>

\*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 2007-2011.

## FY 2013 and 2014 NCI Enrollment Extramural Phase III Research Studies (Only) by Sex/Gender

		<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>FY 2013</b> 222 Trials		<b>Female</b>	<b>72,270</b>	<b>56.92%</b>	<b>48.3%</b>
		<b>Male</b>	<b>54,649</b>	<b>43.04%</b>	<b>51.7%</b>
		<b>Unknown</b>	<b>47</b>	<b>0.04%</b>	
		<b>Total</b>	<b>126,966</b>	<b>100%</b>	<b>100%</b>
		<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>FY 2014</b> 181 Trials		<b>Female</b>	<b>63,366</b>	<b>57.5%</b>	<b>48.3%</b>
		<b>Male</b>	<b>46,771</b>	<b>42.44%</b>	<b>51.7%</b>
		<b>Unknown</b>	<b>69</b>	<b>0.06%</b>	
		<b>Total</b>	<b>110,206</b>	<b>100%</b>	<b>100%</b>

\*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

# NCI Extramural Phase III Research Studies (Only)

FY 2013 – 222 Studies

FY 2014 – 181 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
<b>White</b>	<b>95,637</b>	<b>75.32%</b>	<b>80,578</b>	<b>73.12%</b>	<b>81.4%</b>
<b>Black or African American</b>	<b>16,033</b>	<b>12.63%</b>	<b>14,194</b>	<b>12.88%</b>	<b>10.4%</b>
<b>Asian</b>	<b>9,738</b>	<b>7.67%</b>	<b>9,730</b>	<b>8.83%</b>	<b>6.1%</b>
<b>Hispanic or Latino*</b>	<b>(7,408)</b>	<b>(5.83%)</b>	<b>(7,491)</b>	<b>(6.8%)</b>	<b>(9.5%)</b>
<b>Unknown/Not Reported</b>	<b>3,970</b>	<b>3.13%</b>	<b>4,255</b>	<b>3.86%</b>	
<b>More Than One Race</b>	<b>778</b>	<b>0.61%</b>	<b>709</b>	<b>0.64%</b>	
<b>Amer. Indian/Alaska Native</b>	<b>554</b>	<b>0.44%</b>	<b>503</b>	<b>0.46%</b>	<b>0.4%</b>
<b>Hawaiian/Pacific Islander</b>	<b>256</b>	<b>0.2%</b>	<b>237</b>	<b>0.22%</b>	
<b>Total</b>	<b>126,966</b>	<b>100%</b>	<b>110,206</b>	<b>100%</b>	<b>100%</b>

\*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 2007-2011.

# NCI Intramural Research Studies

FY 2013– 587 Studies

FY 2014 – 588 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	1,709,117	46.1%	1,330,173	43.8%	81.4%
Black or African American	249,223	6.7%	98,582	3.2%	10.4%
Asian	210,372	5.7%	211,863	7.0%	6.1%
Hispanic or Latino*	(121,900)	(3.3%)	(93,595)	(3.1%)	(9.5%)
American Indian/ Alaska Native	7,392	0.2%	4,702	0.2%	0.4%
Hawaiian/Pacific Islander	2,804	0.1%	2,824	0.1%	
More Than One Race	2,323	0.1%	2,101	0.1%	
Unknown/Not Reported	1,523,319	41.1%	1,388,881	45.7%	
<b>Total</b>	<b>3,704,550</b>	<b>100%</b>	<b>3,039,126</b>	<b>100%</b>	<b>100%</b>

\*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 2007-2011.

# CTEP Treatment Trials Enrollment

FY 2013 – 466 Studies

FY 2014 – 392 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
<b>White</b>	<b>19,717</b>	<b>82.02%</b>	<b>16,074</b>	<b>81.01%</b>	<b>81.4%</b>
<b>Hispanic or Latino*</b>	<b>(2,232)</b>	<b>(9.28%)</b>	<b>(1,794)</b>	<b>(9.04%)</b>	<b>(9.5%)</b>
<b>Black or African American</b>	<b>2,021</b>	<b>8.41%</b>	<b>1,688</b>	<b>8.51%</b>	<b>10.4%</b>
<b>Unknown/ Not Reported</b>	<b>1,099</b>	<b>4.57%</b>	<b>979</b>	<b>4.93%</b>	
<b>Asian</b>	<b>941</b>	<b>3.91%</b>	<b>909</b>	<b>4.58%</b>	<b>6.1%</b>
<b>American Indian/ Alaska Native</b>	<b>123</b>	<b>0.51%</b>	<b>107</b>	<b>0.54%</b>	<b>0.4%</b>
<b>Native Hawaiian/ Pacific Islander</b>	<b>85</b>	<b>0.35%</b>	<b>55</b>	<b>0.28%</b>	
<b>More Than One Race</b>	<b>53</b>	<b>0.22%</b>	<b>29</b>	<b>0.15%</b>	
<b>Total</b>	<b>24,039</b>	<b>100%</b>	<b>19,841</b>	<b>100%</b>	<b>100%</b>

\*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 2007-2011.

# CTEP Treatment Trials Enrollment by Gender

**FY 2013**

**466 Studies**

<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>Female</b>	<b>14,479</b>	<b>60.23%</b>	<b>48.3%</b>
<b>Male</b>	<b>9,539</b>	<b>39.68%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>21</b>	<b>0.09%</b>	
<b>Total</b>	<b>24,039</b>	<b>100%</b>	<b>100%</b>

  

<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>Female</b>	<b>11,102</b>	<b>55.95%</b>	<b>48.3%</b>
<b>Male</b>	<b>8,731</b>	<b>44.00%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>8</b>	<b>0.04%</b>	
<b>Total</b>	<b>19,841</b>	<b>100%</b>	<b>100%</b>

**FY 2014**

**392 Studies**

\*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

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

**FY 2013**  
**357 Studies**

<b>Sex/Gender</b>	<b>2013 Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>Male</b>	<b>8,051</b>	<b>56.06%</b>	<b>48.3%</b>
<b>Female</b>	<b>6,299</b>	<b>43.79%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>21</b>	<b>0.15%</b>	
<b>Total</b>	<b>14,371</b>	<b>100%</b>	<b>100%</b>

**FY 2014**  
**315 Studies**

<b>Sex/Gender</b>	<b>2014 Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>Male</b>	<b>7,147</b>	<b>58.69%</b>	<b>48.3%</b>
<b>Female</b>	<b>5,024</b>	<b>41.26%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>6</b>	<b>0.05%</b>	
<b>Total</b>	<b>12,177</b>	<b>100%</b>	<b>100%</b>

Subset of studies reported for 2013 and 2014; Studies include both Males and Females.

\* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

# DCP Trials Enrollment

2013 – 60 Studies

2014 – 60 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count	2014 Percent	US Cancer Incidence**
White	7,755	84.1%	5,159	82.5%	81.4%
Black or African American	906	9.8%	574	9.2%	10.4%
Hispanic or Latino*	(662)	(7.2%)	(449)	(7.2%)	(9.5%)
Asian	263	2.9%	232	3.7%	6.1%
Unknown/ Not Reported	181	2.0%	209	3.3%	
American Indian/ Alaska Native	48	0.5%	48	0.8%	0.4%
Native Hawaiian/ Pacific Islander	22	0.2%	9	0.1%	
More Than One Race	42	0.5%	24	0.4%	
<b>Total</b>	<b>9,217</b>	<b>100%</b>	<b>6,255</b>	<b>100%</b>	<b>100%</b>

\*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 2007-2011.

## DCP Trials Enrollment by Gender

		<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>FY 2013</b>	<b>60 Studies</b>	<b>Female</b>	<b>6,186</b>	<b>67.1%</b>	<b>48.3%</b>
		<b>Male</b>	<b>3,031</b>	<b>32.9%</b>	<b>51.7%</b>
		<b>Unknown</b>	<b>0</b>	<b>0%</b>	
		<b>Total</b>	<b>9,217</b>	<b>100%</b>	<b>100%</b>
		<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>FY 2014</b>	<b>60 Studies</b>	<b>Female</b>	<b>4,689</b>	<b>75.0%</b>	<b>48.3%</b>
		<b>Male</b>	<b>1,566</b>	<b>25.0%</b>	<b>51.7%</b>
		<b>Unknown</b>	<b>0</b>	<b>0%</b>	
		<b>Total</b>	<b>6,255</b>	<b>100%</b>	<b>100%</b>

\* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

## DCP Trials Enrollment by Gender (excluding Gender Specific Trials)

**FY 2013**

**32 Studies**

<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>Female</b>	<b>2,518</b>	<b>74.0%</b>	<b>48.3%</b>
<b>Male</b>	<b>886</b>	<b>26.0%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>0</b>	<b>0%</b>	
<b>Total</b>	<b>3,404</b>	<b>100%</b>	<b>100%</b>

**FY 2014**

**33 Studies**

<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
<b>Female</b>	<b>1,560</b>	<b>53.9%</b>	<b>48.3%</b>
<b>Male</b>	<b>1,336</b>	<b>46.1%</b>	<b>51.7%</b>
<b>Unknown</b>	<b>0</b>	<b>0%</b>	
<b>Total</b>	<b>2,896</b>	<b>100%</b>	<b>100%</b>

Subset of studies reported for 2013 and 2014; Studies include both Males and Females.

\* US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

# DCCPS Epidemiology Studies by Gender

<b>FY 2013</b> <b>369 Studies</b>	<b>Sex/Gender</b>	<b>Count</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
	<b>Female</b>	<b>2,136,223</b>	<b>58.3%</b>	<b>48.3%</b>
	<b>Male</b>	<b>1,522,453</b>	<b>41.6%</b>	<b>51.7%</b>
	<b>Unknown</b>	<b>3,519</b>	<b>0.1%</b>	
	<b>Total</b>	<b>3,662,195</b>	<b>100%</b>	<b>100%</b>
<b>FY 2014</b> <b>354 Studies</b>	<b>Sex/Gender</b>	<b>Count**</b>	<b>Percent of Total</b>	<b>US Cancer Incidence*</b>
	<b>Female</b>	<b>8,253,016</b>	<b>59.2%</b>	<b>48.3%</b>
	<b>Male</b>	<b>4,993,379</b>	<b>35.8%</b>	<b>51.7%</b>
	<b>Unknown</b>	<b>693,192</b>	<b>5.0%</b>	
	<b>Total</b>	<b>13,939,587</b>	<b>100%</b>	<b>100%</b>

\*US Cancer Incidence estimated from SEER Number of Incidence Cases for 2007-2011.

\*\*SEER and Medicare pre-existing Data.

# DCCPS Epidemiology Studies

2013 – 369 Studies

2014 – 354 Studies

Race/Ethnicity	2013 Count	2013 Percent	2014 Count***	2014 Percent	US Cancer Incidence**
<b>White</b>	<b>2,451,743</b>	<b>66.9%</b>	<b>10,512,922</b>	<b>75.4%</b>	<b>81.4%</b>
<b>Black or African American</b>	<b>372,180</b>	<b>10.2%</b>	<b>1,302,240</b>	<b>9.3%</b>	<b>10.4%</b>
<b>Hispanic or Latino*</b>	<b>231,889</b>	<b>(6.3%)</b>	<b>(913,117)</b>	<b>(6.6%)</b>	<b>(9.5%)</b>
<b>Asian</b>	<b>468,370</b>	<b>12.8%</b>	<b>905,952</b>	<b>6.5%</b>	<b>6.1%</b>
<b>Unknown/ Not Reported</b>	<b>326,912</b>	<b>8.9%</b>	<b>900,332</b>	<b>6.5%</b>	
<b>American Indian/ Alaska Native</b>	<b>13,471</b>	<b>0.4%</b>	<b>61,008</b>	<b>0.5%</b>	<b>0.4%</b>
<b>Native Hawaiian/ Pacific Islander</b>	<b>3,795</b>	<b>0.1%</b>	<b>63,854</b>	<b>0.5%</b>	
<b>More Than One Race</b>	<b>25,724</b>	<b>0.7%</b>	<b>193,279</b>	<b>1.4%</b>	
<b>Total</b>	<b>3,662,195</b>	<b>100%</b>	<b>13,939,587</b>	<b>100%</b>	<b>100%</b>

\*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 2007-2011.

\*\*\*Observational Study with increased years reported.

# NCI Population Tracking Accrual Working Group

- Division of Extramural Activities
  - Rajasri Roy, Chair
  - Clarissa Douglas
- Division of Cancer Biology
  - Jennifer Strasburger
- Division of Cancer Control and Population Sciences
  - Mark Alexander
  - Gina Tesauro
- Division of Cancer Prevention
  - Cynthia Whitman
- Division of Cancer Treatment and Diagnosis
  - Rolanda Wade-Ricks
  - Kim Witherspoon
  - Peter Ujhazy
- OD, Office of HIV and AIDs Malignancy
  - Denise Jenkins

# NCI Population Tracking Accrual Working Group Cont'd

- OD, Center to Reduce Cancer Health Disparities
  - Emmanuel Taylor
  - Yolanda Vallejo-Estrada
  - Tiffany Wallace
- OD, Office of Cancer Centers Branch
  - Krzysztof Ptak
- OD, Small Business Innovation Research Development Center
  - Tamar Boghosian