

National Cancer Advisory Board

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

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Overview

- ◆ **Review and Rationale of Policy**
- ◆ **Recent Up-Dates & Implications**
 - **Revised OMB Standards**
 - **NCI Data**
 - **Vote**

NIH Policy on Inclusion of Women and Minorities in Clinical Research

- Mandated by Congress, 1993 PL 103-43 (The NIH Revitalization Act of 1993)
- Ethical principal of justice and importance of balancing research burdens and benefits
- ◆ Women and Minorities must be included in Phase III clinical trials to permit valid analysis
- ◆ Cost is NOT allowed as a reason for exclusion
- ◆ Women and Minorities must be included in all clinical research studies
- ◆ NIH will support outreach efforts to recruit and retain women, minorities, and subpopulations in clinical studies

NIH Revitalization Act of 1993— PL 103-43

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

— Done in odd numbered years

NIH Report Approach

- ◆ **Summary report is prepared centrally by 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**
- ◆ **Compliance**

NCI Procedures for Implementation of NIH Policy: Policy Dissemination

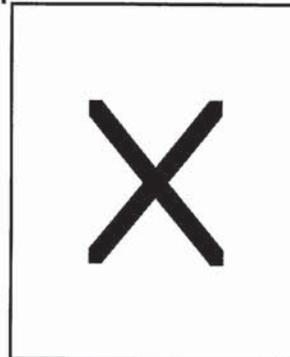
- ◆ **HSA's work with applicants to disseminate requirements (*NIH Guide and NCI and NIH Websites*)**
- ◆ **NCI Extramural staff kept up to date via trans-NIH education programs and desktop distribution of policies and procedures**

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 assure appropriate revisions**
- ◆ **Applications with bars identified in closed NCAB session, and subsequent resolution reported (in 2002, 69 applications required intervention prior to award)**

Funding Decisions

- ◆ **Applications with unacceptable plans cannot be funded – must revise plans!**



NCI Procedures for Implementation of NIH Policy: Post-Award Monitoring

- ◆ **Awardees report actual accrual annually and are encouraged to list trials on NCI Web site**
- ◆ **Accrual is reviewed by each Division, and entered into central collection software**
- ◆ **Staff provide oversight, advice, and assistance if accrual targets diverge from plan**
- ◆ **Staff work with awardees to disseminate findings and encourage new studies**

NCI Implementation of NIH Policy: Aggregate Reporting (1)

- ◆ **NIH requires a format that aggregates all phase III trials, whether treatment, behavioral, or epidemiologic observation**
- ◆ **Aggregate treatment trial data well balanced for gender and race**
- ◆ **Individual trials vary considerably**
- ◆ **Large population-based screening trials swamp aggregate data**

NCI Implementation of NIH Policy: Aggregate Reporting (2)

- ◆ **Proportionate minority accrual harder for clinical trials where subjects have no known disease—e.g. prevention and screening**
- ◆ **NCI funds basic research to address methodology and recruitment issues**
- ◆ **Staff conduct outreach and publish on addressing barriers to accrual**

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 ethnicity category, not race**
- ◆ **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**

Revised Categories

◆ **Ethnic Categories**

- **Hispanic or Latino**
- **Not Hispanic or Latino**

● **Racial Categories**

- **American Indian or Alaska Native**
- **Asian**
- **Black or African American**
- **Native Hawaiian or Other Pacific Islander**
- **White**

Updated NIH Policy on Inclusion

- ◆ **NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October, 2001**
- ◆ **http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm**

Instructions in PHS 398

- ◆ **Inclusion of Women and Minorities Sections must include:**
 - **Subject Selection Criteria & Rationale**
 - **Rationale for Any Exclusions**
 - **Enrollment dates (start and end)**
 - **Outreach Plans for Recruitment**
 - **Proposed Composition Using New Tables**

4/98 INCLUSION TABLE

This report format should NOT be used for data collection from study participants.

Principal Investigator/Project Director _____
(Last, First, Middle)

Grant Number (if known): _____

STUDY TITLE: _____

Total Enrollment: _____ Protocol Number: _____

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

Inclusion Enrollment Report Table

This report format should NOT be used for data collection from study participants.

Study Title: _____

Total Enrollment: _____

Protocol Number: _____

Grant Number: _____

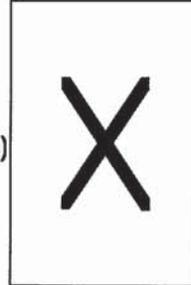
PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)				
Ethnic Category	by Ethnicity and Race			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				*
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree

** These totals must agree

Guidance on New Tables

- ◆ **New application or competing continuation with no plans to collect new/additional data**
 - **May use either:**
 - **New 5/01 Table**
 - **4/98 Version of the Inclusion Table**
- ◆ **Noncompeting applications (Progress Reports) for grants that began before FY 2002**
 - **May use either:**
 - **New 5/01 Table**
 - **4/98 Version of the Inclusion Table**
 - **Use form appropriate for your data**



Accrual to NCI Clinical Trials

- ◆ **Data include epidemiological, population-based interventions, and therapeutic trials according to the NIH definition of clinical research**
- ◆ **NIH requires these data in format aggregating all trials cumulatively**
- ◆ **Populations categories used are those required by regulation**
- ◆ **Current reporting cycle covers data reported in FY2001 and 2002, which represents subjects enrolled in FY2000 and 2001**

**2001 Enrollment
Extramural Research Studies—Old Format
2,277 Studies**

Race/Ethnicity	Number on study	Percent on study	US Population with Cancer
White	1,857,335	60.7%	85.5%
Hispanic	156,736	5.1%	3.5%
Black	193,978	6.3%	9.6%
Asian	572,821	18.7%	1.1%
Native American	7,196	0.2%	0.3%
Other	270,406	8.8%	
Total	3,058,472	100.0%	100.0%

**2002 Enrollment
Extramural Research Studies—Old Format
1,220 Studies**

Race/Ethnicity	Number on study	Percent on study	US Population with Cancer
White	768,701	65.4%	85.5%
Hispanic	81,786	7.0%	3.5%
Black	77,552	6.6%	9.6%
Asian	190,282	16.2%	1.1%
Native American	4,905	0.4%	0.3%
Other	51,802	4.4%	
Total	1,175,028	100.0%	100.0%

**2002 Enrollment
Extramural Research Studies—New Format
922 Studies**

By Race	Number on study	Percent on study	US Population with Cancer
White	1,951,720	61.15%	85.5%
Hispanic			3.5%
Black	268,748	8.42%	9.6%
Hawaiian/Pac Isl	3,388	0.11%	
Asian	217,002	6.80%	1.1%
Native American	48,564	1.52%	0.3%
More than one race	12,772	0.40%	
Other/unknown	689,634	21.61%	
Total	3,191,828	100.00%	100.0%

**Enrollment for All Extramural Studies
by Sex/Gender**

		Gender	Enrolled	%
2001 2,277 Studies	Female		2,342,050	76.58%
	Male		714,129	23.35%
	Unknown		2,293	0.07%
	Total		3,058,472	100.00%
2002 2,142 Studies	Female		3,558,502	85.47%
	Male		803,174	14.36%
	Unknown		7,182	0.16%
	Total		4,368,858	99.99%

Asian Accrual Data

- ◆ More than 350,000 persons on epidemiologic studies in Asia
- ◆ More than 200,000 in U.S.-based epidemiologic studies principally in Hawaii and California

2001 Enrollment - Extramural Research Studies Removing Foreign Asian Grants—Old Format

Race/Ethnicity	Number on study	Percent on study	US Population with Cancer
White	1,857,335	68.8%	85.5%
Hispanic	156,736	5.8%	3.5%
Black	193,978	7.2%	9.6%
Asian	213,740	7.9%	1.1%
Native American	7,196	0.3%	0.3%
Other	270,406	10.0%	
Total	2,699,391	100.0%	100.0%

**CTEP Treatment Trials
Cumulative Enrollment
1995–2002**

Race	Count	Proportion On Trials
American Indian or Alaska Native	578	0.33%
Asian	2,772	1.60%
Black or African American	16,276	9.37%
Hispanic	8,322	4.79%
Native Hawaiian or Other Pacific Islander	667	0.38%
Unknown	4,706	2.71%
White	140,393	80.82%
Grand Total	173,714	100.00%

**CTEP Treatment Trials
Cumulative Enrollment 1995–2002
by Gender**

Gender	95 - 02	Proportion of Participants
Female	102,633	59.08%
Male	70,907	40.82%
Unknown	178	0.10%
Total	173,718	100.00%

**2001 Enrollment
CTEP Treatment Trials**

Race	Count	Proportion On Trials
American Indian or Alaska Native	77	0.29%
Asian	418	1.60%
Black or African American	2,135	8.16%
Hispanic	1,058	4.04%
Native Hawaiian or Other Pacific Islander	56	0.21%
White	21,644	82.74%
Unknown	771	2.95%
Grand Total	26,159	100.00%

**2002 Enrollment
CTEP Treatment Trials**

RACE	Count	Proportion On Trials
American Indian or Alaska Native	105	0.33%
Asian	614	1.95%
Black or African American	2,516	7.98%
Hispanic	1,286	4.08%
Native Hawaiian or Other Pacific Islander	82	0.26%
White	26,046	82.59%
Unknown	889	2.82%
Grand Total	31,538	100.00%

**2001 & 2002
CTEP Treatment Trials Enrollment
by Sex/Gender**

Gender	2001	%
Female	15,931	60.90%
Male	10,211	39.03%
Unknown	17	0.06%
Total	26,159	100.00%

Gender	2002	%
Female	19,636	62.26%
Male	11,840	37.54%
Unknown	62	0.20%
Total	31,538	100.00%

PLCO Study

Race/ Ethnicity	Males Enrolled		Females Enrolled		Totals	
	No	%	No	%	No	%
White	65,188	84.97%	67,400	86.15%	132,588	85.57%
Hispanic	1,606	2.09%	1,215	1.55%	2,821	1.82%
Black	3,370	4.39%	4,338	5.54%	7,708	4.97%
Asian	3,477	4.53%	2,938	3.76%	6,415	4.14%
Am Ind/Ala	186	0.24%	203	0.26%	389	0.25%
Other/Unk	2,889	3.77%	2,144	2.74%	5,033	3.25%
Total	76,716	100.00%	78,238	100.00%	154,954	100.00%

**New Form—2002 Report
Ethnic Categories**

Ethnic Category	Accrual	%	U.S. Pop w Cancer
Hispanic	161,952	5.08%	3.50%
Non-Hispanic	2,021,908	63.36%	96.50%
Other	1,007,044	31.56%	
Total	3,190,904	100.00%	100%

Sex/Gender Enrollments
With and Without All-Male and All-Female Studies

Sex/ Gender	749 Studies 2002		Minus all m & all f studies 602 Studies 2002		US Pop with cancer
	Enrollment	% of total	Enrollment	% of total	
Female	770,040	71.30%	324,807	52.72%	52.00%
Male	308,403	28.56%	289,756	47.03%	48.00%
Other/Unk	1,558	0.14%	1,558	0.25%	

***Subset of studies reported for 2002**

**Intramural Studies
2001 & 2002**

Race/ Ethnicity	2001 - 379 Studies		2002 - 334 Studies		US Pop with cancer
	Enrollment	% of total	Enrollment	% of total	
White	979,596	84.30%	956,243	78.49%	85.50%
Hispanic	28,804	2.48%	27,898	2.29%	3.50%
Black	43,468	3.74%	43,275	3.55%	9.60%
Asian	81,469	7.01%	156,218	12.82%	1.10%
Am Ind/Alaska	3,004	0.26%	2,834	0.23%	0.30%
Other/Unk	25,689	2.21%	31,761	2.61%	
Total	1,162,030	100.00%	1,218,229	100.00%	100.00%

**Intramural Studies
2001 & 2002
Accrual by Sex/Gender**

Sex/ Gender	2001 - 379 Studies		2002 - 334 Studies		US Pop with cancer
	Enrollment	% of total	Enrollment	% of total	
Female	579,637	51.55%	616,801	50.63%	52.00%
Male	542,650	48.27%	598,197	49.10%	48.00%
Other/Unk	2,025	0.18%	3,232	0.27%	