

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.”



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**
- **NCI compliance**



NCI Procedures for Implementation of NIH Policy

POLICY DISSEMINATION

- **HSAAs work with applicants to disseminate requirements (*NIH Guide and 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

PREAWARD 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 1999, 26 applications required intervention prior to award.**



NCI Procedures for Implementation of NIH Policy

POST AWARD MONITORING

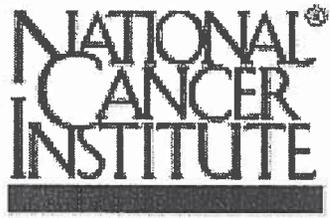
- **Awardees report actual accrual annually and are encouraged to list trials in PDQ**
- **Accrual is reviewed by each Division, and entered into central collection software**
- **Staff provide oversight, advice and assistance if accrual targets diverge from plan**
- **Staff work with awardees to disseminate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



NCI Procedures for Implementation of NIH Policy

AGGREGATE REPORTING

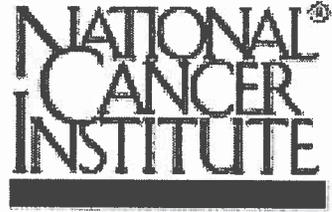
- **NIH requires a format that aggregates all phase III trials whether treatment, behavioral or epidemiologic observation**
- **Overall treatment trial data well balanced for gender**
- **Individual trials vary considerably**
- **Large population based screening trials swamp aggregate data.**



NCI Procedures for Implementation of NIH Policy

AGGREGATE REPORTING (Continued)

- Minority accrual challenging for clinical trials where subjects have no known disease, e.g. prevention and screening**
- NCI now funds basic research to address methodologic and recruitment issues**
- Staff conduct outreach and publish on addressing barriers to accrual**



NCI Enrollment for all Extramural Research Protocols by Race/Ethnicity (1998)

6947 protocols

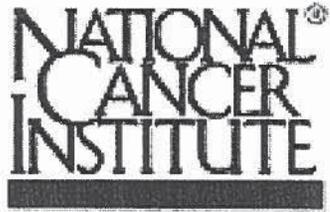
Race/Ethnicity	Number on Study	Percent on Study	US Population with Cancer
White	1,007,328	45.9%	85.5%
Hispanic	96,150	4.4%	3.5%
Black	193,231	8.8%	9.6%
Asian	779,992	35.6%	1.1%
Native American	2,295	0.1%	0.3%
Other	113,355	5.2%	
Total	2,192,351	100.0%	100.0%



NCI Enrollment by Gender for All Extramural Research Protocols (1998)

6947 protocols

Gender	Number on study	Percent on study	US Population with Cancer
Female	1,755,255	80.1%	52.0%
Male	428,225	19.5%	48.0%
Unknown	8,871	0.4%	
TOTAL	2,192,351	100.0%	100.0%



Asian Accrual

- **More than 426,000 persons on epidemiologic studies in Asia**
- **More than 300,000 in epidemiologic studies principally in Hawaii and California**



Net NCI enrollment for Extramural Research Protocols Minus Foreign Asian Populations (1998)

Race/Ethnicity	Number on Study	Percent on Study	US Population with Cancer
White	1,007,328	57.0%	85.5%
Hispanic	96,150	5.5%	3.5%
Black	193,231	11.0%	9.6%
Asian	353,630	20.0%	1.1%
Native American	2,295	0.1%	0.3%
Other	113,355	6.4%	
Total	1,765,989	100.0%	100.0%



NCI Enrollment for all Phase III Extramural Research Protocols by Race/Ethnicity (1998)

201 protocols

Race/Ethnicity	Number on Study	Percent on Study	US Population with Cancer
White	102,730	84.0%	85.5%
Hispanic	6,499	5.3%	3.5%
Black	7,744	6.3%	9.6%
Asian	2,643	2.2%	1.1%
Native American	444	0.4%	0.3%
Other	2,241	1.8%	
Total	122,301	100.0%	100.0%



NCI Enrollment by Gender for all Phase III Extramural Research Protocols (1998)

201 protocols

Race/Ethnicity	Number on Study	Percent on Study	US Population with Cancer
White	102,730	84.0%	85.5%
Hispanic	6,499	5.3%	3.5%
Black	7,744	6.3%	9.6%
Asian	2,643	2.2%	1.1%
Native American	444	0.4%	0.3%
Other	2,241	1.8%	
Total	122,301	100.0%	100.0%



NCI Cooperative Group Treatment Trials Enrollment By Race/Ethnicity (1998)

Race/Ethnicity	Number	Proportion onto Trials	US Population with Cancer
White	16,361	79.8%	85.5%
Hispanic	1,166	5.7%	3.5%
Black	2,082	10.2%	9.6%
Asian	420	2.0%	1.1%
Native American	79	0.4%	0.3%
Other	401	2.0%	
Total	20,509	100.0%	100.0%



NCI Clinical Treatment Trials Enrollment by Gender (1998)

Gender	Number on study	Percent on study	US Population with Cancer
Female	9,803	47.8%	52.0%
Male	10,706	52.2%	48.0%
TOTAL	20,509	100.0%	100.0%