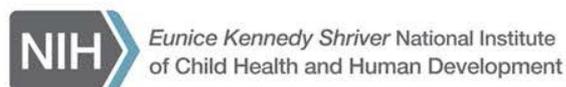


Triennial Advisory Council Report Certifying Compliance with the NIH Policy on Inclusion Guidelines



Eugene G. Hayunga, Ph.D.
Director, Office of Extramural Policy
Division of Extramural Research, NICHD
January 25, 2019

NIH Revitalization Act of 1993 (PL103-43)



The Director of NIH shall:

- ensure that women and members of minorities and their subpopulations are included in all human subject research;
- for Phase III clinical trials, ensure that women and minorities and their subpopulations must be included such that valid analyses of differences in intervention effect can be accomplished;
- not allow cost as an acceptable reason for excluding these groups; and,
- initiate programs and support for outreach efforts to recruit these groups into clinical studies.

(Federal Register, 28 March 1994; 59 FR: 14508-14513)



Contents of the Report:

- I. Background/Overview: NICHD Mission & Research Portfolio
- II. Strategies for Ensuring Compliance
- III. Enrollment Data
- IV. Additional Information:
 - Inclusion policy changes related to the 21st Century Cures Act
 - Publications with analysis of gender/race/ethnicity
 - Projects specifically addressing inclusion of women and/or minority populations
 - Other highlighted information



- Total numbers of NICHD clinical research projects and Phase III trials
- Aggregate data showing total enrollment of women/men and racial/ethnic groups for:
 - Extramural
 - Intramural
 - Clinical research projects
 - Phase III trials
 - U.S. and non-U.S. enrollment

Enrollment Overview



NICHD Clinical Research Projects			
FY	Total	U.S. Site	Non-U.S. Site
2016	1,070	896	108
2017	1,129	929	96
2018	1,121	862	109

NICHD Phase III Clinical Trials			
FY	Total	U.S. Site	Non-U.S. Site
2016	40	19	20
2017	45	31	12
2018	30	18	6



Total Enrollment for All NICHD Extramural and Intramural Clinical Research Projects

FY	Total Enrollment	Females	%	Males	%	Unknown	%
2016	2,784,689	1,882,262	67.6	856,033	30.7	46,394	1.7
2017	1,212,881	757,047	62.4	447,090	36.9	8,744	0.7
2018	1,293,100	778,357	60.2	503,448	38.9	11,295	0.9



Inclusion of minorities

Total Enrollment for All NICHD Extramural and Intramural Clinical Research Projects (2018 data, U.S. sites by race)

Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American
2018	Female	6,002	1.3	19,182	4.0	96,276	20.2
2018	Male	4,731	1.5	11,767	3.7	64,469	20.5
2018	Unknown	44	0.9	44	0.9	258	5.3
Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
6,922	1.5	265,271	55.6	22,438	4.7	60,670	12.7
2,538	0.8	166,322	52.9	19,297	6.1	45,312	14.4
16	0.3	758	15.7	63	1.3	3,654	75.5



Total Enrollment for All NICHD Extramural and Intramural Clinical Research Projects (2018 data, U.S. sites by ethnicity)

Year	Sex Gender	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2018	Female	360,290	75.6	62,837	13.2	53,634	11.2
2018	Male	238,226	75.8	47,327	15.1	28,883	9.2
2018	Unknown	1,140	23.6	344	7.1	3,353	69.3



- Inclusion policy changes related to the 21st Century Cures Act
- Research related to Intellectual and Developmental Disabilities (IDD)
- Research addressing Health Disparities
- Intramural research
- Projects & publications addressing sex/gender, racial and/or ethnic differences



- Continued monitoring
- Attention to project milestones
- New tools for data analysis using RCDC terms
- Inclusion across the lifespan



- NICHD has working processes in place.
- Enrollment data show substantial inclusion of women and minorities across a broad spectrum of NICHD-supported research.
- Focus of Inclusion Policy:
 - Science driven
 - Ethical basis
 - Partnership

Acknowledgements



Sandra Delcore

LaShaun Thompson

Constantine Stratakis

Forbes Porter

Della Hann

Meredith Temple-O'Connor

Melissa Parisi

Rebecca Clark

Sarah Glavin

James Griffin

Lisa Kaeser

Charisee Lamar

Ronna Popkin

Numerous staff in NICHD, OER, ORWH

