NIGMS COMPLIANCE WITH THE NIH POLICY ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH
2015 Biennial Report

I. Background and Overview

The NIH Revitalization Act of 1993 (PL 103-43) included a provision that women and minorities must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research is provided. Included in this Act is a statement indicating that "**The advisory council of each national research institute shall prepare biennial reports describing the manner in which the institute has complied with this section."** This report serves to document how NIGMS has continued to comply with this policy requirement. It is the ninth such report reviewed by the National Advisory General Medical Sciences Council.

Under the current policy, all NIH-supported biomedical and behavioral research that meets the following definition of clinical research must address the inclusion of women and minorities in study populations. Clinical research is defined as:

1) Patient-oriented research.
2) Epidemiologic and behavioral studies; and
3) Outcomes research and health services research.

NIGMS supports research that is the foundation for disease diagnosis, treatment and prevention. Ergo, the majority of NIGMS-supported research does not involve human subjects. For example, 65 (1.4%) of the 4,531 research grants awarded by NIGMS in fiscal year 2013 reported involvement of human subjects in research activities, and 80 (1.7%) of the 4,588 research grants awarded by NIGMS in fiscal year 2014 reported involvement of human subjects in research activities. Furthermore, the majority of NIGMS-supported human subjects research activities do not meet the NIH definition of clinical research and thus, the NIH policy on the inclusion of women and minorities as subjects in clinical research applies to only a small number of NIGMS grants. In FY2013, 83 of the 211 active grants involving human subjects research activities met the eligibility criteria for population tracking. In FY2014, 105 of the 246 active grants involving human subjects research activities required population tracking.

II. Strategies for Ensuring Compliance

A. Peer Review

Plans for inclusion of women and minorities are evaluated as part of the peer review process. In FY2013, inclusion plans in 20 of the 675 NIGMS applications with human subjects research activities that were evaluated by peer reviewers were found to be unacceptable. In FY2014, inclusion plans in 19 of the 646 NIGMS applications with human subjects research activities evaluated by peer reviewers were designated as unacceptable. In FY2013, one application with an inclusion plan found to be unacceptable by peer reviewers was funded after program staff approved a revised inclusion plan. In FY2014, three applications with inclusion plans designated unacceptable by peer reviewers were funded after program staff approved revised inclusion plans.

B. NIGMS Procedures for Ensuring Compliance

Prior to funding, applications involving human subjects are reviewed by both program and grants management staff to determine if population tracking is required. Both competing and non-competing grant electronic checklists include questions regarding inclusion tracking as well as instructions for determining if a grant is eligible for population tracking. Population tracking data is entered into the NIH-wide tracking database by the NIGMS Tracking Coordinator (Justin Rosenzweig) from data forwarded by the program director assigned to the eligible grant. All NIH population tracking data is maintained by the NIH Electronic Research Administration (eRA) system in a population tracking module. Our ongoing oversight efforts include:

1) Web-based information and instruction on the NIGMS intranet.
2) Continued education at both the group and individual level for members of the research community whose research is affected by this policy.
3) NIGMS Representation on the eRA Population Tracking Users Group (Justin Rosenzweig, grants management senior specialist) and Inclusion Operating Procedures Workgroup (Sarah Dunsmore, program director and NIGMS human subjects point person).

C. Staff Training on the Utilization of the Tracking System within NIGMS

NIGMS ensures personnel are appropriately trained to monitor and document tracking and inclusion requirements by providing ongoing staff training on both NIH and NIGMS policy/procedure and reinforcing the knowledge of all staff through periodic training sessions. Dr. Dunsmore provides individualized training to program staff on an as-needed basis, particularly for newly-hired program directors, and Mr. Rosenzweig provides similar instruction to grants management staff. The NIH Office of Extramural Research maintains an internet (Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation Page) and intranet (Policy Topic: Inclusion of Women and Minorities in Clinical Research-Policy Implementation Page) site with appropriate references and training materials.

III. Analysis and Interpretation of Data

Table 1 and Table 2 summarize data submitted to the NIH inclusion tracking database in fiscal years 2013 and 2014. Table 1 shows data submitted in FY2013 for extramural clinical research protocols performed in FY2012; Table 2 shows data submitted in FY2014 for extramural clinical research protocols performed in FY2013. NIGMS does not support intramural clinical research. In FY2013 and FY2014, NIGMS did not support any NIH-defined Phase III clinical trials.

The number of tracked protocols was relatively stable for FY2007 (92), FY2008 (90) and FY2009 (93). The number of tracked protocols declined by approximately 20% in FY2010 (72) and declined by another 20% in FY2011 (58). The decline in the number of tracked protocols between FY2009 and FY2010 is due to a combination of a decrease in awarded grants subject to population tracking and a change in the reporting status of ongoing awards while the decline in the number of tracked protocols between FY2010 and FY2011 is almost entirely due to changes in the reporting status of ongoing awards. In FY2012, the number of tracked protocols increased to 136. Twenty-three grants that contain tracked protocols were transferred from the former National Center for Research Resources to NIGMS in FY2012 accounting for 30% of this increase. The remainder of the increase (70%) was due to changes in the reporting status of ongoing awards as the number of new awards subject to population tracking was stable in FY2011 (13) and FY2012 (11). The number of new awards subject to population tracking increased approximately two-fold in FY2013 (26) and FY2014 (22) compared to the previous reporting period (FY2011 and FY2012). As a consequence, the number of tracked protocols was slightly increased in FY2013 (148) and FY2014 (142) as compared to FY2012 (136).

At the level of enrollment of individual subjects, the large increase in aggregate enrollment between FY2013 (45,896) and FY2014 (118,913) can largely be accounted for by a clinical study of ductal carcinoma in situ funded by a COBRE award to the University of Vermont and State Agricultural College that utilized 67,114 individually identifiable patient records in FY2014.

IV. Additional Information

A new NIH Inclusion Management System (IMS) was launched on October 17, 2014 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-086.html; http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-005.html). Key changes include:

1) Inclusion enrollment report forms received with competing application submissions will automatically populate the IMS.

2) NIH grantees completing their RPPR (Research Progress Performance Report) will be prompted in Item G.4.b to access and update inclusion records directly in IMS.

3) Grantees will be able to access their inclusion enrollment data through the IMS, found through the eRA Commons Status page, and can review or update their inclusion data as needed.

4) NIH will migrate ongoing enrollment information from the previous Population Tracking Module to the IMS.

V. Publications with analyses on sex/gender, race, and/or ethnicity that cite NIGMS support

1. Racial differences in breast cancer, cardiovascular disease, and all-cause mortality among women with ductal carcinoma in situ of the breast. Breast Cancer Res Treat 148:407-413, 2014. Supported by P20 GM103644.
2. The impact of follow-up type and missed deaths on population-based cancer survival studies for Hispanics and Asians. J Natl Cancer Inst Monogr. 2014:210-217, 2014. Supported by P20 GM103440.
3. Prevalence of metabolic syndrome among Filipino-Americans: a cross-sectional study. Appl Nurs Res 26:192-197, 2013. Supported by P20 GM103440.
4. A cohort study evaluating the implications of biology, weight status and socioeconomic level on global self-esteem competence among female African-American adolescents. J Natl Black Nurses Assoc 24:1-8, 2013. Supported by P20 GM103501.
5. All-cause, cardiovascular, and cancer mortality in western Alaska Native people: western Alaska Tribal Collaborative for Health (WATCH). Am J Public Health 104:13341340, 2014. Supported by P30 GM103325.
6. Genetic variant in folate homeostasis is associated with lower warfarin dose in African Americans. Blood 124:2298-2305, 2014. Supported by R24 GM061374.
7. Genome-wide association analyses suggest NELL1 influences adverse metabolic response to HCTZ in African Americans. Pharmacogenomics J 14:35-40, 2014. Supported by UO1 GM074492.
8. Genetic variants associated with warfarin dose in African-American individuals: a genome-wide association study. Lancet 382:790-796, 2013. Supported by U19GM061390, RC2 GM092618, UO1GM061393, UO1 GM074492, R24GM061374, RO1 GM081488.
9. Pharmacogenetics in American Indian populations: analysis of CYP2D6, CYP3A4, CYP3A5, and CYP2C9 in the Confederated Salish and Kootenai Tribes. Pharmacogenet Genomics 23:403-414, 2013. Supported by UO1 GM092676, PO1 GM099568.
10. Urinary incontinence: its assessment and relationship to depression among community-dwelling multiethnic older women. ScientificWorldJournal 2014:708564, 2014. Supported by SO6 GM048680, SC3 GM094075.

Table 1 NIGMS FY2013 Aggregate Enrollment Data

Total Number of Active NIGMS Protocols with Enrollments: 148

Total NIGMS Enrollment: 45,896

	Total of All Subjects by Race								Total of All Subjects By Ethnicities			
	American Indian-Alaska Native	Asian	Black or African American	Hawaiian-Pacific Islander	White	More than One Race	Unknown-Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown-Not Reported	Total
Female	2,896	859	2,954	68	15,316	408	2,291	24,792	19,718	3,134	1,940	24,792
	11.68%	3.46%	11.92%	0.27%	61.78%	1.65%	9.24%	54.02%	79.53%	12.64%	7.83%	54.02%
Male	1,293	637	2,583	31	12,187	360	3,007	20,098	14,142	3,297	2,659	20,098
	6.43%	3.17%	12.85%	0.15%	60.64%	1.79%	14.96%	43.79%	70.37%	16.40%	13.23%	43.79%
Unknown	69	12	4		22	4	895	1,006	88	7	911	1,006
	6.86%	1.19%	0.40%		2.19%	0.40%	88.97%	2.19%	8.75%	0.70%	90.56%	2.19%
Total	4,258	1,508	5,541	99	27,525	772	6,193	45,896	33,948	6,438	5,510	45,896
	9.28%	3.29%	12.07%	0.22%	59.97%	1.68%	13.49%	100%	73.97%	14.03%	12.01%	100%

Table 2 NIGMS FY2014 Aggregate Enrollment Data

Total Number of Active NIGMS Protocols with Enrollments: 142

Total NIGMS Enrollment: 118,913

	Total of All Subjects by Race								Total of All Subjects By Ethnicities			
	American Indian-Alaska Native	Asian	Black or African American	Hawaiian-Pacific Islander	White	More than One Race	Unknown-Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown-Not Reported	Total
Female	1,377	595	8,942	53	74,063	633	9,673	95,336	82,931	3,807	8,598	95,336
	1.44%	0.62%	9.38%	0.06%	77.69%	0.66%	10.15%	80.17%	86.99%	3.99%	9.02%	80.17%
Male	1,026	539	2,291	56	14,519	432	3,269	22,132	16,090	3,530	2,512	22,132
	4.64%	2.44%	10.35%	0.25%	65.60%	1.95%	14.77%	18.61%	72.70%	15.95%	11.35%	18.61%
Unknown	133	5	6		7	4	1290	1,445	38	788	619	1,445
	9.20%	0.35%	0.42%		0.48%	0.28%	89.27%	1.22%	2.63%	54.53%	42.84%	1.22%
Total	2,536	1,139	11,239	109	88,589	1,069	14,232	118,913	99,059	8,125	11,729	118,913
	2.13%	0.96%	9.45%	0.09%	74.50%	0.90%	11.97%	100%	83.30%	6.83%	9.86%	100%