

FOGARTY INTERNATIONAL CENTER POPULATION TRACKING BIENNIAL REPORT (2013-2014)

INTRODUCTION

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 studies. The Revitalization Act reinforced the existing NIH policies but with four major differences:

- That NIH ensure that U.S. women and minorities and their subpopulations be included in all clinical research;
- That U.S. women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to allow for valid analyses of differences in intervention effects;
- That cost is not an acceptable reason for excluding these groups; and,
- That NIH initiates programs and support for outreach efforts to recruit and retain U.S. women and minorities and their subpopulations as participants in clinical studies.

The NIH Revitalization Act of 1993 stipulates that the advisory councils of each NIH Institute and Center (IC) prepare a biennial report describing activities of their staff to comply with the Act as well as results of those activities reflected in funded human subject research enrollment statistics. This report presents the Fogarty International Center's (FIC) activities related to fulfilling its responsibilities under the Act in Fiscal Years (FY) 2013 and 2014.

Mission Statement

[Fogarty International Center's](#) (FIC) mission is dedicated to advancing the mission of the [National Institutes of Health](#) by supporting and facilitating global health research conducted by U.S. and investigators in low- and middle-income countries (LMICs), building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs.

Vision Statement

Fogarty's programs provide funding to conduct research and train researchers in a variety of global health areas. Through these programs, Fogarty and its partners are building sustainable research capacity in low- and middle-income countries (LMICs).

STRATEGIES FOR ENSURING POLICY COMPLIANCE WITH INCLUSION GUIDELINES

The NIH Revitalization Act of 1993 and subsequent reports from the Government Accounting Office and Congress stipulated that each Institute and Center at NIH must ensure that its staff and the extramural investigators it funds understand the requirements of the Act regarding the conduct of clinical research. Dr. Maria Said, FIC Inclusion Policy Representative, along with Katrina Blair, Program Analyst and Francine Sellers, Lead Extramural Support Assistant for the FIC Division of International Research and Training (DITR) are charged to oversee compliance with the Inclusion Guidelines and provide guidance to the DITR Program Officers. Each DITR Program Officer is

advised to read the resources provided by the Office of Extramural Research at http://grants2.nih.gov/grants/funding/women_min/women_min.htm. Dr. Said is a member of the Extramural Advisory Working Group that reviews NIH compliance and the NIH e-Population Tracking Users Group that oversees the NIH tracking system to capture human subjects research inclusion data and recommends changes, as needed. Program officers assist investigators to ensure that human subjects research target and enrollment information is included in their grant applications and progress reports. Staff training on the use of the population tracking system occurs primarily through “in-house” instruction from experienced staff.

The Center for Scientific Review (CSR) staff and relevant review staff at partner ICs make every effort to comply with the NIH Inclusion Policy while conducting FIC grant application reviews. FIC does not traditionally provide support for intervention trials; however, a number of FIC programs support population-based research and large cohort studies that are primarily epidemiological or behavioral in nature. Each application that proposes human subjects research is reviewed for adherence to the inclusion requirements. Review criteria stipulate that the priority score assigned reflect the application’s efforts to adequately address inclusion issues. In August 2014, the Office of Extramural Research issued updated [Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity and Age in Clinical Research](#) with new instructions for peer reviewers and Scientific Review Administrators to review NIH-defined Phase III clinical trial research proposals to meet inclusion requirements and identify issues related to valid analyses for sex/gender and/or racial/ethnic groups. It emphasizes that inclusion on the basis of sex/gender, race, and ethnicity, as well as the inclusion of children should be guided by the scientific aims of the study. The review requirements of these guidelines are included in all review documents and discussed with peer reviewers prior to review of research applications.

Applications that fail to meet the requirements for inclusion automatically receive a NIH database code to bar funding. For most awards, program staff is able to remedy deficiencies found during review by securing additional information from applicants. FIC Grants management staff insures that no awards are made until inclusion requirements are satisfied.

Gender and minority enrollment data from FIC-supported research grants involving human subjects are submitted by the principal investigator are updated as part of annual progress reporting. This data is verified in the NIH Population Tracking Database by FIC program staff with authorized access. If the enrollment data is missing, a program officer contacts the investigator to correct the error. FIC grants management staff insure that a continuation award is not made until the enrollment data is submitted.

In October 2014, a new Inclusion Management System (IMS) for reporting sex/gender, race, and ethnicity information required by the NIH Policy on the Inclusion of Women and Minorities in Clinical Research was released. Grantees enter inclusion data directly into this electronic system for monitoring by program staff.

ANALYSIS AND INTERPRETATION OF DATA

Inclusion data was reported for grants conducting human subject’s research in the following FIC programs:

Brain Disorders in the Developing World: Research across the Lifespan (BRAIN) (R21, R01)

This program supports research on neurological disorders across the lifespan in low- and middle-income countries (LMIC). The objectives are to: 1) Conduct research on nervous system development, function and impairment at any life stage or across the lifespan on topics relevant to LMICs; 2) Build research capacity among LMIC partners and institutions involved in a specific research project; and 3) Encourage research that leads to appropriate, innovative diagnostics, prevention and treatment strategies.

Ecology and Evolution of Infectious Diseases (EEID) (R01)

A unique multi-agency competitive research grant program administered jointly by National Science Foundation (NSF) and FIC that supports multidisciplinary research and training to enhance the ability to predict and control infectious diseases in their full ecological and public health contexts, including environmental, evolutionary and demographic changes, and public health, medical and veterinary interventions. Projects integrate lab studies, field research and mathematical modeling to understand disease transmission.

Fogarty International Research Collaboration Award (FIRCA) (R03): Basic/Biomedical Sciences and Behavioral/Social Sciences

This program was established to foster international collaborations between NIH funded scientists and scientists in low- and middle- income countries (LMIC) to conduct global health research of mutual interest and benefit and build research capabilities that foster productive research at the foreign institution.

Limited Competition for the Global Research Initiative Program for New Foreign Investigators (GRIP) (R01): Basic/Biomedical Sciences, Behavioral/Social Sciences

This program is intended to promote productive development of foreign investigators from LMICs trained in the U.S. or in their home countries through NIH funded research or research training programs, to enhance the scientific research infrastructure in LMICs, and to stimulate research on a wide variety of high priority health-related issues of importance in those countries.

Medical Education Partnership Initiative (MEPI) (R24)

This program was established with support from the President's Emergency Plan for AIDS Relief (PEPFAR) and NIH to provide direct support to African institutions to strengthen clinical and research capacity in medical education in Sub-Saharan Africa by (1) Improving the quality of clinical education and clinical care; (2) Enabling graduate medical students to remain in their home countries to practice, serve as faculty, and/or conduct research related to the implementation of PEPFAR and other public health priorities; and (3) Enhancing the recruitment and retention of qualified academic faculty through partnerships and research opportunities.

International Tobacco or Health Research and Capacity Building Program (R01)

This program aims to encourage trans-disciplinary research to the international tobacco epidemic and to reduce the global burden of morbidity and mortality caused by tobacco use. The main objectives are: (1) to foster collaboration between US and foreign scientists; (2) to address the burden of tobacco consumption in low & middle income countries; and (3) to perform both research and capacity building in an integrated way.

TARGET AND ACCRUAL DATA FOR FY2013 AND FY2014

FIC supported research studies that meet the NIH inclusion criteria include those funded through R01, R21, R24, R03 and U01 mechanisms. All FIC supported research studies involve awards to a domestic grantee with a foreign component or a direct foreign grantee. To reduce the likelihood of over-reporting (i.e. human subjects of foreign site reported as a racial or ethnic group considered as a U.S. minority group) staff responsible for verifying inclusion data are instructed to specify the country where enrollment occurred. In recent years, there has been a trend by FIC supported investigators to either not report the race or mark as race unknown for enrolled participants to minimize misclassifying subjects as U.S. minorities.

Aggregate Data Tables

The aggregate enrollment data for Fogarty International Center (FIC) supported research involving human subjects is provided on pages 6-12 for FY2013 and FY2014.

FY 2013 Inclusion Data

In FY2013, a total of 20,184 participants were enrolled in 25 protocols (Table 1). All of the protocols reported human subjects enrolled at foreign sites. 60.26% (12,163) of those enrolled were female and 38.25% (7,721) were male. Gender was reported as unknown for 300 participants (1.49%). Race was unknown or not reported for 2.1% of the enrollees; however, in the remaining cases where race was characterized, the percentage of minorities by race was 97.22% and by ethnicity was 4.03% (Table 1) according to the definition of U.S. racial and ethnicity categories. Among the 25 protocols with enrollments reported by FIC in FY2013, none had sex-specific protocols.

FY 2014 Inclusion Data

In FY2014, a total of 37,166 research participants were enrolled in 31 protocols (Table 2). All of the protocols reported human subjects enrolled at foreign sites. 60.73% (22,571) of the participants enrolled were females and 38.46% (14,295) were males. Gender was reported as unknown for 300 research participants (0.81%). 6.21% of the aggregate enrollment data had unknown or not reported race data. In the cases where race was identified, the percentage of minorities by race enrolled was 77.79% and by ethnicity was 14.43% according to definition of U.S. racial and ethnicity categories. 1 protocol was only enrolled female participants at a foreign site (data not shown). Therefore, 0.23% (84) of all female participants in all the protocols were in female-only studies.

Methodology for Data Compilation

To compile aggregate FIC inclusion data, a set of pre-fabricated reports generated by the NIH Population Tracking Module were utilized. Reports from the Query, View, Report (QVR) grants database were used by staff to search and view detailed information about grant applications and awards, supplemented the Population Tracking module data with information on international sites and granular detail of the grants.

**Table 1. Total Number of Extramural Protocols in FY2013: Total of All Subjects Reported Using the 1997 OMB Standards
Number of Protocols with Enrollment Data: 25**

Gender	Total of All Subjects by Race							Count	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	0	813	10,892	0	75	332	51	12,163	11,665	452	46	12,163
	0%	6.68%	89.55%	0%	0.62%	2.73%	0.42%	60.26%	95.91%	3.72%	0.38%	60.26%
Male	0	732	6,618	0	80	237	54	7,721	7,310	362	49	7,721
	0%	9.48%	85.71%	0%	1.04%	3.07%	0.7%	38.25%	94.68%	4.69%	0.63%	38.25%
Unknown	0	0	0	0	0	0	300	300	300	0	0	300
	0%	0%	0%	0%	0%	0%	100%	1.49%	100%	0%	0%	1.49%
Total	0	1,545	17,510	0	155	569	405	20,184	19,275	814	95	20,184
	0%	7.65%	86.75%	0%	0.77%	2.82%	2.01%	100%	95.5%	4.03%	0.47%	100%

**Table 2. Total Number of Extramural Protocols in FY2014: Total of All Subjects Reported Using the 1997 OMB Standards
Number of Protocols with Enrollment Data: 31**

Gender	Total of All Subjects by Race							Count	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	398	16,448	0	3,738	947	1,038	22,571	19,631	2,860	80	22,571
	0.01%	1.76%	72.87%	0%	16.56	4.2%	4.6%	60.73%	86.97%	12.67%	0.35%	60.73%
Male	0	301	10,050	0	2,212	762	970	14,295	11,778	2,504	13	14,295
	0%	2.11%	70.3%	0%	15.47%	5.33%	6.79%	38.46%	82.39%	17.52%	0.09%	38.46%
Unknown	0	0	0	0	0	0	300	300	300	0	0	300
	0%	0%	0%	0%	0%	0%	100%	0.81%	100%	0%	0%	0.81%
Total	2	699	26,498	0	5,950	1,709	2,308	37,166	31,709	5,364	93	37,166
	0.01%	1.88%	71.3%	0%	16.01%	4.6%	6.21%	100%	85.32%	14.43%	0.25%	100%

**Table 3
FY 2013 Aggregate Enrollment Data
Extramural Research Protocols**

**Total Subjects Reported Using the 1997 OMB Standards
Number of Protocols with Enrollment Data: 25
Excluding Male-Only and Female-Only Protocols**

Gender	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	0	813	10,892	0	75	332	51	12,163	11,665	452	46	12,163
	0%	6.68%	89.55%	0%	0.62%	2.73%	0.42%	60.26%	95.91%	3.72%	0.38%	60.26%
Male	0	732	6,618	0	80	237	54	7,721	7,310	362	49	7,721
	0%	9.48%	85.71%	0%	1.04%	3.07%	0.7%	38.25%	94.68%	4.69%	0.63%	38.25%
Unknown	0	0	0	0	0	0	300	300	300	0	0	300
	0%	0%	0%	0%	0%	0%	100%	1.49%	100%	0%	0%	1.49%
Total	0	1,545	17,510	0	155	569	405	20,184	19,275	814	95	20,184
	0%	7.65%	86.75%	0%	0.77%	2.82%	2.01%	100%	95.5%	4.03%	0.47%	100%

Table 4
FY 2014 Aggregate Enrollment Data
Extramural Research Protocols

Total Subjects Reported Using the 1997 OMB Standards
Number of Protocols with Enrollment Data: 30
 Excluding Male-Only and Female-Only

GENDER	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	314	16,448	0	3,738	947	1,038	22,487	19,547	2,860	80	22,487
	0.01%	1.4%	73.14%	0%	16.62%	4.21%	4.62%	60.64	86.93%	12.72%	0.36%	60.64%
Male	0	301	10,050	0	2,212	762	970	14,295	11,778	2,504	13	14,295
	0%	2.11%	70.3%	0%	15.47%	5.33%	6.79%	38.55	82.39%	17.52%	0.09%	38.55%
Unknown	0	0	0	0	0	0	300	300	300	0	0	300
	0%	0%	0%	0%	0%	0%	100%	0.81%	100%	0%	0%	0.81%
Total	2	615	26,498	0	5,950	1,709	2,308	37,082	31,625	5,364	93	37,082
	0.01%	1.66%	71.46%	0%	16.05%	4.61%	6.22%	100%	85.28%	14.47%	0.25%	100%

Table 5
Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total Number of Applications Reviewed	(#)	110	1	37	32	157	86	86	31
Number of Applications with Human Subjects	(#)	6	1	18	27	17	52	85	25
Number (percent) of Applications approved by IRG as submitted	(#)	6	1	18	25	17	52	84	25
	(%)	100%	100%	100%	92.59%	100%	100%	98.82%	100%
Number (percent) of Applications with unacceptable minority- only inclusion	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of Applications with unacceptable sex/gender-only inclusion	(#)	0	0	0	2	0	0	0	0
	(%)	0%	0%	0%	7.41%	0%	0%	0%	0%
Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion	(#)	0	0	0	0	0	0	1	0
	(%)	0%	0%	0%	0%	0%	0%	1.18%	0%
Total Number (percent) of Applications with unacceptable minority inclusion	(#)	0	0	0	0	0	0	1	0
	(%)	0%	0%	0%	0%	0%	0%	1.18%	0%
Total Number (percent) of Applications with unacceptable sex/gender inclusion	(#)	0	0	0	2	0	0	1	0
	(%)	0%	0%	0%	7.41%	0%	0%	1.18%	0%
Total Number (percent) of unacceptable Applications as submitted	(#)	0	0	0	2	0	0	1	0

	(%)	0%	0%	0%	7.41%	0%	0%	1.18%	0%
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Table B. Extramural Research Awards: Bars-To-Funding and Resolutions

Council		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total number of awards	(#)	36	1	5	9	38	3	7	5
Number of awards involving Human Subjects	(#)	1	1	3	9	4	0	7	4
Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted	(#)	1	1	3	9	4	0	7	4
	(%)	100%	100%	100%	100%	100%	0%	100%	100%
Number (percent) of awards where minority-only bar-to-funding was removed by program staff (M_U)	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of awards where sex/gender-only bar-to-funding was removed by program staff (G_U)	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of awards where both minority AND sex/gender bar-to-funding were removed by program staff	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where minority bar-to-funding was removed by program staff	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where sex/gender bar-to-funding was removed by program staff	(#)	0	0	0	0	0	0	0	0

	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where bar-to-funding was removed	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%

Fogarty International Center (FIC) Advisory Board Certification: The FIC Advisory Board, at the February 9-10, 2015 meeting, was informed of their responsibilities for compliance with the 2015 Biennial Report Certifying Compliance with the NIH Policy on Inclusion Guidelines. The FIC Advisory Board reviewed the FIC Inclusion Report by email and a majority certified that FIC is in compliance with the NIH policy on inclusion.