

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

**2019 TRIENNIAL ADVISORY COUNCIL REPORTS
CERTIFYING COMPLIANCE WITH THE
NIH POLICY ON INCLUSION GUIDELINES**



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**Fogarty International Center's (FIC) Monitoring Adherence
to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research
as Reported in FY2016 – FY2018**

I. Background/Overview

A. 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. investigators 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.

B. Description of FIC programs:

FIC's programs provide funding to U.S. and foreign organizations/investigators to conduct research and train scientists in a variety of global health areas. Through these programs, FIC and its partners are building sustainable research capacity in LMICs. Inclusion data was reported for grants conducting human subjects research in the following FIC programs:

- **Brain Disorders in the Developing World: Research across the Lifespan (BRAIN) (R21)**

This program supports research on neurological disorders across the lifespan in low- and middle-income countries (LMIC). The objectives are to: conduct research on nervous system development, function and impairment at any life stage or across the lifespan on topics relevant to the LMICs; build research capacity among LMIC partners and institutions involved in a specific research project; and 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 the 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.

- **International Tobacco and Health Research and Capacity Building Program (R01)**

This program aims to encourage trans-disciplinary research on the international tobacco epidemic, with the goal of reducing the global burden of morbidity and mortality caused by tobacco use. The main objectives are: to foster collaboration between US and foreign scientists; to address the burden of tobacco consumption in LMICs; and to perform both research and capacity building in an integrated way.

- **International Research Scientist Development Award (IRSDA) (K01)**

The goal of the International Research Scientist Development Award (IRSDA) is to provide support and protected time (three to five years) to advanced postdoctoral U.S. research scientists and recently-appointed U.S. junior faculty for an intensive, mentored research career development experience in a LMIC.

- **Emerging Global Leader Award (K43)**

The purpose of the Fogarty Emerging Global Leader Award is to provide research support and protected time (three to five years) to an early career research scientist from a LMIC who holds a junior faculty position at an LMIC academic or research institution. LMIC scientists from any health-related discipline are eligible to apply and must propose career development activities and a research project that is relevant to the health priorities of their country under the mentorship of LMIC and U.S. mentors.

- **Global Noncommunicable Diseases and Injury Across the Lifespan: Exploratory Research (R21)**

The Global Noncommunicable Diseases and Injury Across the Lifespan research program aims to support innovative, collaborative biomedical or behavioral/social science research in the areas of noncommunicable diseases (NCDs) and injury throughout life in LMICs. Basic, clinical and translational research including implementation science approaches and interdisciplinary research on the intersection of NCDs, HIV or other communicable diseases and noncommunicable diseases, are encouraged, in addition to specific NCD or injury focused areas.

- **Global Environmental and Occupational Health (GEOHealth) (U01)**

The Global Environmental and Occupational Health (GEOHealth) program supports the development of institutions in LMICs serving as regional hubs for collaborative research, data

management, training, curriculum and outreach material development, and policy support around high-priority local, national and regional environmental and occupational health threats.

- **Mobile Health: Technology and Outcomes in Low- and Middle-Income Countries (R21)**

Mobile Health: Technology and Outcomes in Low- and Middle-Income Countries supports exploratory and developmental research to develop or adapt innovative mobile health (mHealth) technology specifically suited for LMICs, and the health-related outcomes associated with implementation of the technology. The program aims to contribute to the evidence base for the use of mobile technology to improve clinical outcomes and public health, while building research capacity in LMICs and establishing research networks in this area.

II. Strategies for Ensuring Compliance

C. Peer Review and resolution of inclusion concerns:

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific [guidance](#) on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race, and ethnicity.

Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the minutes of the review session. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, program staff notify Principal Investigators, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding and an award is not issued until an acceptable resolution is received.

D. Program Monitoring and Grants Management Oversight

Prior to an award, program officials/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide consultation to the PIs when necessary. For NIH-defined Phase III clinical trials,

program officials/program directors monitor the requirement for sex/gender and race/ethnicity analyses in applications and annual progress reports. Grants management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file.

E. IC training approaches.

- a. Institute Program Officials/Program Directors and Scientific Review Officers attended the May 11, 2018 training, Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts. Staff have also accessed the archived training on the NIH staff intranet.
- b. FIC Program Officials/Program Directors completed the NIH Core Curriculum training and are regularly updated on the policy changes that affect inclusion monitoring through IC training.

F. Analysis and Interpretation of Data

Aggregate Data Tables

The aggregate enrollment data for FIC supported research involving human subjects for FY2016-2018 is provided in the appendix. All the data presented has been reported by the FIC-funded investigators. Furthermore, all the participants in the FIC-funded Inclusion Enrollment Records (IERs) are foreign, with very few exceptions. Therefore, coding by U.S. racial and ethnic categories was incorrectly reported by FIC-funded investigators. Instead, all the participants should have been reported as race/ethnicity unreported/unknown, with very few exceptions.

Inclusion Enrollment Records for FIC-funded awards for FY 2016-2018

A. FIC supported research studies that met the NIH inclusion criteria were funded through R01, R21, K01, K43, and U01 mechanisms. The FIC supported research studies involved awards to a domestic grantee institution with a foreign component, or directly to a foreign grantee institution. In recent years, significant improvement has been noticed in the quality of data being entered by FIC supported investigators, with limited numbers of participants marked with race as unknown or not reported.

B. IC aggregate inclusion data FY 2016-2018

Inclusion data FY2016

FIC recorded a total of 29 IER, with 17 reported to have enrolled participants (Table 2-1). One site was inadvertently marked as domestic by the PI. In addition, three (3) IERs reported to have female-only enrollment and zero reported to have male-only enrollment. Prospective data for enrollment by race and ethnicity showed a total of 29,149 research participants enrolled in FY2016, of this one project reported to have over 14,000 participants (Table 5-1-1-C). All the participants had gender reported, with 57.7% (16,816) as female and 42.3% (12,333) as male. In the cases where race was identified, the percentage of minorities enrolled by race was 97.5% for females and 100% for males. Ethnicity (according to definition of U.S. racial and ethnicity categories) was reported as unknown for 2.5% (423) of female participants (Table 5-1-1-C).

Inclusion data FY2017

Forty-four (44) IERs were reported in FY17, of which thirty records reported enrollment with all the participants at non-U.S. sites. Of these, 8 reported to have female only and one study reported male only enrollment (Table 2-1). All the participants were enrolled at a foreign site, with a total of 4,606 females (66.4%) and 2,334 males (33.6%).

Race was identified for 94.8% (4,368) of females and 98.1% (2,289) of males, with 251 females and 63 males missing ethnicity data (Table 5-1-1-C).

Inclusion data for FY2018

Records for IERs in 2018 increased to 57, with 4 records reporting enrollment at a U.S. site. Two of these were inadvertently incorrectly entered by the PI as having U.S.-based enrollment and one project is a repeat record. Only one project was correctly identified with participants at a U.S. site (Table 2-1). These errors were discovered after the completion of data analysis and will be corrected in the next iteration of the report. Total number of participants enrolled in FIC-funded studies in FY2018 was 16,678 (9,178 female and 7,258 male). Gender was reported as unknown for 233 research participants (1.4%) and 0.4% of the aggregate enrollment data had unknown or not reported race data (Table 5-1-1-C). Race and ethnicity data for FY2018 indicate 97.3% of females and 98.8% of male participants had racial and ethnicity data reported. One participant record in FY2018 has unknown or unreported race category (5-1-1-C).

In FY2018, one project began enrollment into an NIH-Defined Phase III Clinical Trial. A total of 88 participants (3 females and 85 males) were enrolled in FY2018 (Table 5-2-2-C).

C. Summaries of the inclusion data for each of the required tables:

1. Table 2-1: presents information on the total number of active inclusion data records (IERS) for the years 2016-2018. The data is organized by IERS with and without enrollment for the specific year, in addition to indicating U.S. and foreign enrollment.
2. Table 5-1-1-C, Enrollment for All NIH-Defined Clinical Research, by Sex/Gender, Race, and Ethnicity. The data in this table shows prospective participant enrollment by racial and ethnic category. In addition, this table shows aggregated totals and percentages by race and ethnicity.
3. Table 5-2-2-C. Enrollment for NIH-Defined Extramural and Intramural Phase III Trials by Sex/Gender, Race, and Ethnicity. This table shows the number of active extramural NIH-Defined Phase III Clinical Trials in each of the fiscal years listed. The table also shows the racial and ethnic group of the participants.

D. For the listing of FIC's funded research by RCDC category, please refer to <https://report.nih.gov/RISR/#/>.

III. Additional information

G. Policy changes related to the 21st Century Cures Act.

The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities as Subjects in Clinical Research on November 28, 2017, to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised policy, now called the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, applies to individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated after this date. The 21st Century Cures Act amended the frequency of the Report of the NIH

Director on the inclusion of women and minorities from biennial to triennial. Thus, this first triennial report provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018. Section IV of the [Report of the Advisory Committee on Research on Women's Health](#) includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2015 and 2016.

Section 2: Metrics Based on Inclusion Data Records (IERs)

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male-only and Female-only*
2016	29	12	17	1	16	3	0	14
2017	44	14	30	0	30	8	1	21
2018	57	16	41	4	37	6	4	31

*Inclusion Data Records (IERs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).

Total Enrollment: All NIH-Defined Clinical Research

Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	16,389	97.5	16,816	57.7	2,292	13.6	14,101	83.9	423	2.5
2016	Male	12,327	100.0	12,333	42.3	1,838	14.9	10,489	85.0	6	0.0
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	4,368	94.8	4,606	66.4	4,115	89.3	240	5.2	251	5.4
2017	Male	2,289	98.1	2,334	33.6	2,194	94.0	77	3.3	63	2.7
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2018	Female	8,939	97.3	9,187	55.1	8,939	97.3	238	2.6	10	0.1
2018	Male	7,174	98.8	7,258	43.5	6,632	91.4	559	7.7	67	0.9
2018	Unknown	232	99.6	233	1.4	233	100.0	0	0.0	0	0.0

Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	Female	40	0.2	973	5.8	2,365	14.1	0	0.0	5,679	33.8	612	3.6	7,147	42.5
2016	Male	0	0.0	562	4.6	1,766	14.3	0	0.0	1,803	14.6	504	4.1	7,698	62.4
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	6	0.1	1,987	43.1	2,034	44.2	0	0.0	264	5.7	161	3.5	154	3.3
2017	Male	0	0.0	844	36.2	1,364	58.4	0	0.0	75	3.2	4	0.2	47	2.0
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2018	Female	63	0.7	2,352	25.6	6,037	65.7	0	0.0	284	3.1	429	4.7	22	0.2
2018	Male	1	0.0	1,095	15.1	5,417	74.6	0	0.0	591	8.1	106	1.5	48	0.7
2018	Unknown	21	9.0	97	41.6	107	45.9	0	0.0	0	0.0	7	3.0	1	0.4

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Site Enrollment: All NIH-Defined Clinical Research

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2016	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

2017	Unknown	0	0.0	0	0.0								
2018	Female	3	100.0	3	3.4	3	100.0	0	0.0	0	0.0		
2018	Male	85	100.0	85	96.6	85	100.0	0	0.0	0	0.0		
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2016	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2018	Female	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2018	Male	0	0.0	85	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 5-2-3-C. ALL Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2016	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

