

Fogarty International Center's (FIC) Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019 – FY2021

I. Background/Overview

A. Mission Statement:

The Fogarty International Center (FIC) 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) (R01 and R21)

This program supports research on neurological disorders across the lifespan in LMICs. 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/AIDS 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.

Fogarty HIV Research Training Program (D43)

The overall goal of the Fogarty HIV Research Training Program is to strengthen the human capacity to contribute to the ability of institutions in LMICs to conduct HIV-related research on the evolving HIV-related epidemics in their country and to compete independently for research funding.

Reducing Stigma to Improve HIV/AIDS Prevention, Treatment and Care in Low- and Middle-Income Countries (R21)

The purpose of this FOA is to stimulate research on interventions to reduce HIV/AIDS-associated stigma and its impact on the prevention and treatment of HIV/AIDS and on the quality of life of People Living with HIV/AIDS (PLWH). Specifically, this initiative supports research on novel stigma reduction interventions, impact of stigma on adolescent and/or youth

health, strategies to cope with the complex burden of stigmatization due to HIV and one or more comorbidities/coinfections, effects of stigma on family or caregivers of PLWH, and innovative and improved stigma measurement in the context of implementation of an intervention).

HIV-associated Noncommunicable Diseases Research at Low- and Middle-Income Country Institutions (R21)

This program supports locally relevant research in critical areas of HIV-associated noncommunicable diseases at LMIC institutions, to enhance research capacity and build a network of researchers both within and across LMICs to address this critical burden. This initiative is expected to stimulate new research on the interplay between HIV and development of NCDs in persons living with HIV (PLWH).

International Bioethics Research Training Program (D43)

This program supports LMIC-U.S. collaborative institutional bioethics doctoral and postdoctoral research training programs that incorporate didactic, mentored research and career development components to prepare trainees for positions of scholarship and leadership at health research institutions in LMICs.

II. Strategies for Ensuring Compliance

A. Peer Review process and how the IC works to resolve 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. For NIH-defined Phase III clinical trials, enrollment goals are further

assessed for plans to conduct analyses of intervention effects among sex/gender, racial, and ethnic groups. 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. The Fogarty International Center's (FIC) Advisory Council performs the second level of review and makes recommendations for funding to the FIC Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for FIC. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

B. 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 when necessary. For NIH-defined Phase III clinical trials, program officials/program directors monitor requirements for plans and reporting of 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.

C. IC training approaches.

Institute Program Officials/Program Directors and Scientific Review Officers attended the 2020 Inclusion Training for Program Staff and the 2020 Inclusion Training for Review Staff in April 2020. Staff may access the archived training on the NIH staff intranet.

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.

III. Analysis and Interpretation of Data

- A. The aggregate enrollment data for FIC supported research** involving human subjects for FY2019-2022 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 reported by FIC-funded investigators, does not correctly reflect the racial/ethnic data. Instead, all the participants should have been reported as race/ethnicity unreported/unknown, with very few exceptions.

B. Inclusion Enrollment Records for FIC-funded awards for FY 2019-2021

FIC supported research studies that met the NIH inclusion criteria were funded through R01, R21, K01, K43, D43 and U01 mechanisms. The FIC supported research studies included 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 gender as not reported.

C. IC aggregate inclusion data FY 2019-2021:

Inclusion data FY2019

In FY2019, FIC recorded a total of 105 Inclusion Data Records (IERs) with 65 reported to have enrolled participants (Table 2-1). During the same year, one FIC award conducted four (4) pilot studies with the use of U.S. domestic participants, the rest of the 61 IERs represented only foreign human subjects' participation. Twelve (12) IERs reported to have only female enrollment and six (6) included only males. In addition, in FY2019 total two studies included a Phase III protocol (Table 2-2), with 6 females and 125 males all of whom were reported as Asian (Table 5-2-2-C).

Total numbers of enrolled participants in FY2019 were 19,743 with 58.7% female and 38.7 male subjects (Table 3-1-A). Five hundred and eleven (511) or 2.6% of participants did not have their sex/gender category recorded. However, all the participants in the Phase III clinical trials had their gender and racial categories recorded (Table 5-2-2-C; see explanation in section III, paragraph A). Of these Phase III studies two (2) are required to complete sex/gender and race/ethnicity analyses (Table 2-3). Furthermore, in the

cases where race was identified, the percentage of minority participants enrolled was 89% for females, 90.4% for males, and 83.8% of unknown (Table 5-1-1-C).

Inclusion data FY2020

In FY2020, FIC recorded more than a doubling of IERs, with 213 records. Of these 115 reported human subjects' enrollment, with seventeen (17) female-only and eight (8) male-only IERs (Table 2-1). Of these records, four (4) were reported to be Phase III studies (Table 2-2), where three (3) had active enrollment. All four Phase III studies were with male participants only with a total of 584 subjects, where 51.4% were reported as Asian and 48.5% as more than one race (Table 5-2-2-C). Out of the four (4) Phase III studies in FY2020, two (2) are required to conduct sex/gender and race/ethnicity analyses (Table 2-3).

The total enrollment numbers have also increased, doubling from FY2019 to record 40,374 participants (Table 3-1-A). These numbers indicated a significant increase in human subject data collection. It is worth noting that the quality of data has improved, with percentage of "sex/gender unknown" record having fallen to 1.8% (from 2.6% in FY2019) (Table 5-1-1-C). However, one change in the data is the increase in the percentage of unknown records for racial categories, while the reports of minority participation is above 95% for males, females and unknown (Table 5-1-1-C; see explanation in section III, paragraph A).

Inclusion data FY2021

We continued to see an increase in IERs in FY2021, with a total of 248 records (Table 2-1). Of these, 144 reported enrollment and 3 pilot studies (part of one grant) continued with U.S. domestic data collection. There has also been an increase of Phase III protocols, with five (5) studies recorded in FY2021, with 2 having active enrollment (Table 2-2). These Phase III studies enrolled 325 females and 1,219 males with 100% minority participation, where 100% of females were recorded as Black, while 75.4% of

males were recorded as Black and 24.5% as Asian (Table 5-2-2-C). Of these Phase III studies, five (5) are required to conduct valid analysis on race ethnicity and sex/gender (Table 2-3).

Overall enrollment numbers have also increased from previous years to a total of 45,455 (Table 3-1-A), and we continue to see an improvement in reporting of sex/gender with only 0.8% (345) of all cases recorded as unknown (Table 5-1-1-C). Furthermore, in FY2021, over 95% reported to be a minority, with race and ethnicity data showing that of the 56% of females, majority were Black (72.7%), followed by unknown (17.5%), White (5.3%), Asian (4%), and more than one race (0.4%) (Table 5-1-1-C; see explanation in section III, paragraph A). For males, the breakdown is a bit more even with 53.9% reported as Black, 23.5% as unknown, followed by 12.7% Asian, 7.9% as White, and 2.1 as more than one race (Table 5-1-1-C).

D. Summaries of the appended tables show enrollment data for fiscal years (FY) 2019 through 2021:

- a. Table 2-1: presents information on the total number of inclusion data records (IERs) for the fiscal years 2019-2021. The data is organized by IERs with and without active enrollment for the specific year, in addition to indicating U.S. or foreign enrollment.
- b. Table 2-2: presents information on the total numbers of Phase III studies in fiscal years 2019-2021. The table also shows U.S. and foreign enrollment and whether studies have male or female participants.
- c. Table 2-3: presents information on the number of Phase III studies requiring valid analysis by sex/gender or race/ethnicity.
- d. Table 3-1-A: presents total enrollment numbers for all IERs for fiscal years 2019-2021. The table also provides information on proportions and numbers of participants according to their reported sex/gender category.

e. 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.

f. 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.

E. For a listing of the FIC-funded research by RCDC categories, please refer to:

<https://report.nih.gov/RISR/>.

F. Additional information

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.

Appendix:

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 Fiscal Years 2019 and 2021

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*
2019	105	40	65	4	61	12	6	47
2020	213	98	115	3	112	17	8	90
2021	248	104	144	3	141	25	8	111

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

Total Inclusion Data Records (IERS): All NIH-Defined Phase III Trials

Table 2-2. Total Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between Fiscal Years 2019 and 2021

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*
2019	2	1	1	0	1	0	0	1
2020	4	1	3	0	3	0	3	0
2021	5	3	2	0	2	0	1	1

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

Total Inclusion Data Records (IERS): All NIH Phase III Clinical Trials

Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERS	IERS Requiring Race Ethnicity Valid Analysis	% IERS Requiring Race Ethnicity Valid Analysis	IERS Requiring Sex Gender Valid Analysis	% IERS Requiring Sex Gender Valid Analysis
2019	2	2	100.0	2	100.0
2020	4	2	50.0	2	50.0
2021	5	5	100.0	5	100.0

Current methodology to monitor valid analysis began in 2019 and differs from what was used in 2018 (N/A in 2018). Plans for valid analysis methodologies specified in the project application are reported for all IERS, including IERS that have no reported actual enrollment at the time of reporting.

Section 3: Metrics Based on Aggregate Enrollment: Sex/Gender

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2019 and 2021

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2019	19,743	11,588	58.7	7,644	38.7	511	2.6	3,465	17.6	528	2.7	8,123	41.1	7,116	36.0
2020	40,374	22,492	55.7	17,168	42.5	714	1.8	5,369	13.3	1,037	2.6	17,123	42.4	16,131	40.0
2021	45,455	25,465	56.0	19,645	43.2	345	0.8	7,025	15.5	1,311	2.9	18,440	40.6	18,334	40.3

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

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

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	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
2019	Female	10,309	89.0	11,588	58.7	135	1.2	2,532	21.9	6,415	55.4	0	0.0	1,287	11.1	431	3.7	788	6.8
2019	Male	6,913	90.4	7,644	38.7	3	0.0	1,679	22.0	3,450	45.1	0	0.0	1,256	16.4	427	5.6	829	10.8
2019	Unknown	428	83.8	511	2.6	99	19.4	158	30.9	132	25.8	0	0.0	1	0.2	39	7.6	82	16.0
2020	Female	21,434	95.3	22,492	55.7	135	0.6	2,213	9.8	15,039	66.9	0	0.0	1,066	4.7	583	2.6	3,456	15.4
2020	Male	16,451	95.8	17,168	42.5	3	0.0	3,024	17.6	8,757	51.0	0	0.0	1,242	7.2	566	3.3	3,576	20.8
2020	Unknown	713	99.9	714	1.8	99	13.9	160	22.4	403	56.4	0	0.0	1	0.1	39	5.5	12	1.7
2021	Female	24,205	95.1	25,465	56.0	0	0.0	1,021	4.0	18,520	72.7	0	0.0	1,355	5.3	113	0.4	4,456	17.5
2021	Male	18,696	95.2	19,645	43.2	4	0.0	2,489	12.7	10,586	53.9	1	0.0	1,545	7.9	403	2.1	4,617	23.5
2021	Unknown	344	99.7	345	0.8	0	0.0	2	0.6	324	93.9	0	0.0	6	1.7	0	0.0	13	3.8

Fiscal Year	Sex Gender	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	11,588	58.7	10,569	91.2	1,009	8.7	10	0.1
2019	Male	7,644	38.7	5,893	77.1	1,684	22.0	67	0.9
2019	Unknown	511	2.6	429	84.0	0	0.0	82	16.0
2020	Female	22,492	55.7	18,698	83.1	3,707	16.5	87	0.4
2020	Male	17,168	42.5	12,485	72.7	4,448	25.9	235	1.4
2020	Unknown	714	1.8	702	98.3	12	1.7	0	0.0
2021	Female	25,465	56.0	20,128	79.0	4,559	17.9	778	3.1
2021	Male	19,645	43.2	12,828	65.3	5,697	29.0	1,120	5.7
2021	Unknown	345	0.8	326	94.5	18	5.2	1	0.3

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

All 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

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	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
2019	Female	6	100.0	6	4.6	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2019	Male	125	100.0	125	95.4	0	0.0	125	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2019	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Male	584	100.0	584	100.0	0	0.0	300	51.4	0	0.0	0	0.0	0	0.0	284	48.6	0	0.0
2020	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Female	325	100.0	325	21.0	0	0.0	0	0.0	325	100.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Male	1,219	100.0	1,219	79.0	0	0.0	300	24.6	919	75.4	0	0.0	0	0.0	0	0.0	0	0.0
2021	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	6	100.0	6	4.6	6	100.0	0	0.0	0	0.0
2019	Male	125	100.0	125	95.4	125	100.0	0	0.0	0	0.0
2019	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Male	584	100.0	584	100.0	300	51.4	284	48.6	0	0.0
2020	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Female	325	100.0	325	21.0	0	0.0	0	0.0	325	100.0
2021	Male	1,219	100.0	1,219	79.0	300	24.6	0	0.0	919	75.4
2021	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0