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 FY2022 – FY2024

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 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.

Chronic, Noncommunicable Diseases and Disorders Research Training (NCD-Lifespan; D43)

The goal of the NDC-Lifespan program is to sustainably strengthen the NCD research capacity of the LMIC institutions, and to train in-country experts to develop and conduct research on NCDs across the lifespan, with the long-range goal of developing and implementing evidence-based interventions relevant to their countries.

Dissemination and Implementation Research Program (R21)

Dissemination and Implementation Research Program is an NIH-wide initiative, focused on supporting studies that will identify, develop, and/or test strategies for overcoming barriers to the adoption, adaptation, integration, sustainability, scale-up, and spread of evidence-based interventions, practices, programs, tools, treatments, guidelines, and policies (herein referred to collectively as evidence-based interventions).

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/R33)

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.

Interventions for Stigma Reduction to Improve HIV/AIDS Prevention, Treatment and Care in Low- and Middle-Income Countries (R01)

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 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, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex, 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, 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 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.

NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for program staff. Staff may access the training on the NIH staff intranet. FIC Program Officials/Program Directors are regularly updated on the policy changes that affect inclusion monitoring through IC training. New POs/PDs are introduced to the inclusion monitoring processes and are assisted in monitoring inclusion for their programs and grants.

III. Analysis and Interpretation of Data

A. The aggregate enrollment data for FIC supported research involving human subjects for FY2022-2024 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 of the racial and ethnic categories was done according to the closest alignment with the U.S. racial and ethnic categories reported by FIC-funded investigators but may not fully accurately reflect the racial/ethnic data.

B. Inclusion Enrollment Records for FIC-funded awards for FY 2022-2024

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 including 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 sex or race/ethnicity unknown or not reported.

C. IC aggregate inclusion data FY 2022-2024:

Inclusion data FY2022

In FY2022, FIC recorded a total of 290 IERs with 169 reported to have enrolled participants (Table 2-1). Twenty-nine (29) IERs reported to have female only enrollment and eight (8) included only males. There were no studies with U.S. enrolment. In addition, a total of four studies included a Phase III protocol in the same year (Table 2-2), where all were without any active IERs.

Total numbers of enrolled participants in FY2022 were 45,794, with 57.3% female and 42% male subjects (Table 3-1-A). Three hundred and fourteen (314) or 0.7% of participants did not have their sex category recorded, which is in-line with previous years. Furthermore, in the cases where race was identified, the percentage of minority participants enrolled was 97.5% for females, 99.6% for males, and 99.7% unknown (Table 5-1-1-C).

Inclusion data FY2023

In FY2023, FIC recorded a slight decrease in reported IERs, with 216 records. Of these 93 reported human subjects' enrollment, with eleven (11) female-only and nine (9) male-only IERs (Table 2-1). Of these records, four (4) included Phase III studies (Table 2-2), where one (1) had active enrollment. All 388 subjects in this active IER did not have their sex reported, with 100% in the Black/African American racial category (Table 5-2-2-C).

Out of the four (4) Phase III studies in FY2022, three (3) are required to conduct sex and race/ethnicity analyses (Table 2-3).

The total enrollment numbers have decreased by about 50% from FY2022 to 22,172 participants (Table 3-1-A). These numbers indicate a significant decrease in human subject data collection. It is worth noting that the quality of data also declined, with percentage of "sex unknown" record increasing to 2.5% (from 0.7% in FY2022; Table 5-1-1-C). The numbers of unknown/not reported race and ethnicity also increased, although minority participants were reported at above 92% for males, females and unknown (Table 5-1-1-C; see explanation in section III, paragraph A).

Inclusion data FY2024

The number of IERs in FY2024 remained stable, with a total of 218 records (Table 2-1). Of these, 96 reported active enrollments. An increase of Phase III protocols was recorded in FY2024, with seven (7) studies (one with active enrollment; Table 2-2). These Phase III studies enrolled 231 females and 221 males with 100% minority participation, where 100% of females and males were recorded as Black (Table 5-2-2-C). Of these Phase III studies, five (5) are required to conduct valid analysis on race/ethnicity and sex (Table 2-3).

Overall enrollment numbers have also increased from previous year to a total of 34,212 (Table 3-1-A), with an improvement in reporting of sex with only 0.2% (84) of all cases recorded as unknown (Table 5-1-1-C). Furthermore, in FY2024, 64% of male participants were Black, 30.7% Asian, 1.2% American Indian Alaska Native and 1.4% White. For females, 80.4% were Black, 14.6 Asian, 3.2% White and 1.6% were American Indian Alaska Native. Of the participants where sex was unknown/not reported 70 participants were Black and 14 did not have their race/ethnicity reported (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) 2022 through 2024:

a. Table 2-1: presents information on the total number of inclusion data records (IERs) for the fiscal years 2022-2024. 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 2022-24. 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 or race/ethnicity.

d. Table 3-1-A: presents total enrollment numbers for all IERs for fiscal years 2022-2024. The table also provides information on proportions and numbers of participants according to their reported sex category.

e. Table 5-1-1-C, Enrollment for All NIH-Defined Clinical Research, by Sex, 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, 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. RCDC categories

For a listing of the FIC-funded research by RCDC categories, please refer to: https://report.nih.gov/RISR/. Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category will be available on the RCDC Inclusion Statistics Report website (https://report.nih.gov/RISR/) at a later date but are available by request. These data will now be published annually at this website.

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 2022 and 2024

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*
2022	290	121	169	0	169	29	8	132
2023	216	123	93	2	91	11	9	73
2024	218	122	96	2	94	14	12	70

*Inclusion Data Records (IERs) excluding male only and female only include unknown sex, and combination of unknown and any sex(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 2022 and 2024

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*
2022	4	4	0	0	0	0	0	0
2023	4	3	1	0	1	0	0	1
2024	7	6	1	0	1	0	0	1

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

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

Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2022 and 2024

Fiscal Year	Total IERs	IERs Requiring Race Ethnicity Valid Analysis	% IERs Requiring Race Ethnicity Valid Analysis	IERs Requiring Sex Valid Analysis	% IERs Requiring Sex Valid Analysis
2022	4	4	100.0	4	100.0
2023	4	3	75.0	3	75.0
2024	7	5	71.4	5	71.4

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: SexTable
3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2022 and 2024

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
2022	45,794	26,230	57.3	19,250	42.0	314	0.7	7,479	16.3	1,176	2.6	18,751	40.9	18,074	39.5
2023	22,172	12,516	56.4	9,091	41.0	565	2.5	3,331	15.0	654	2.9	9,185	41.4	8,437	38.1
2024	34,212	22,764	66.5	11,364	33.2	84	0.2	8,301	24.3	1,183	3.5	14,463	42.3	10,181	29.8

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

Section 4: Total Enrollment: All NIH-Defined Clinical Research
Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex, by Race and Ethnicity

Fiscal Year	Sex	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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	25,579	97.5	26,230	57.3	0	0.0	2,846	10.9	22,503	85.8	0	0.0	696	2.7	4	0.0	181	0.7	25,540	97.4	226	0.9	464	1.8
2022	Male	19,179	99.6	19,250	42.0	1	0.0	3,026	15.7	15,493	80.5	1	0.0	580	3.0	83	0.4	66	0.3	18,561	96.4	653	3.4	36	0.2
2022	Unknown	313	99.7	314	0.7	0	0.0	10	3.2	303	96.5	0	0.0	0	0.0	0	0.0	1	0.3	313	99.7	0	0.0	1	0.3
2023	Female	11,891	95.0	12,516	56.4	37	0.3	3,303	26.4	8,494	67.9	0	0.0	637	5.1	28	0.2	17	0.1	11,780	94.1	66	0.5	670	5.4
2023	Male	9,056	99.6	9,091	41.0	42	0.5	3,168	34.8	5,531	60.8	1	0.0	54	0.6	280	3.1	15	0.2	8,740	96.1	333	3.7	18	0.2
2023	Unknown	520	92.0	565	2.5	5	0.9	12	2.1	503	89.0	0	0.0	0	0.0	0	0.0	45	8.0	470	83.2	5	0.9	90	15.9
2024	Female	22,040	96.8	22,764	66.5	364	1.6	3,326	14.6	18,294	80.4	0	0.0	722	3.2	29	0.1	29	0.1	18,789	82.5	391	1.7	3,584	15.7
2024	Male	11,205	98.6	11,364	33.2	141	1.2	3,487	30.7	7,270	64.0	4	0.0	162	1.4	282	2.5	18	0.2	10,924	96.1	416	3.7	24	0.2
2024	Unknown	70	83.3	84	0.2	0	0.0	0	0.0	70	83.3	0	0.0	0	0.0	0	0.0	14	16.7	70	83.3	0	0.0	14	16.7

The data presented in this report shows 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 by Race and Ethnicity

Fiscal Year	Sex	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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	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	0	0.0	0	0.0	0	0.0
2022	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	0	0.0	0	0.0	0	0.0
2023	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	0	0.0	0	0.0	0	0.0
2023	Unknown	388	100.0	388	100.0	0	0.0	0	0.0	388	100.0	0	0.0	0	0.0	0	0.0	0	0.0	388	100.0	0	0.0	0	0.0
2024	Female	231	100.0	231	51.1	0	0.0	0	0.0	231	100.0	0	0.0	0	0.0	0	0.0	0	0.0	231	100.0	0	0.0	0	0.0
2024	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	0	0.0	0	0.0	0	0.0