# National Institute of Allergy and Infectious Diseases (NIAID) Report on Monitoring Adherence to the National Institutes of Health (NIH) Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in Fiscal Years 2022 – 2024

## I. Background/Overview

### A. NIAID Mission Statement

The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to conduct and support basic and clinical research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 65 years, NIAID-supported research has led to many new scientific advances, including novel diagnostics, therapies, vaccines, and other technologies that have improved the health of millions of people in the United States and beyond. In addition to managing its complex and robust research portfolio, NIAID plays a key role in protecting public health through its unique mandate that requires the Institute to respond to emerging public health threats.

### B. NIAID Portfolio

NIAID conducts and supports an extensive research portfolio that spans four extramural and three intramural divisions that guide the Institute's scientific activities. Through its clinical research programs, NIAID aims to expand understanding of the human immune system and leverage this knowledge to better understand, diagnose, prevent, and treat both infectious and immunologic diseases. Many infectious and immunologic diseases disproportionately or differently impact specific populations, including women, children, older adults, and people from certain racial or ethnic populations. Thus, NIAID strives to enhance inclusion of varied populations to ensure research findings from its clinical research benefits all individuals.

### C. NIH Inclusion Policies Background

The NIH inclusion policies, first published in 1987 and codified by the NIH Revitalization Act of 1993, mandate the inclusion of women and minorities in clinical research. The Office of Management and Budget (OMB) Directive 15, introduced in 1997 and applied to clinical research reporting beginning in fiscal year (FY) 2001, established new standards for reporting race and ethnicity, distinguishing ethnicity from race and introducing specific categories for each. According to the new reporting standards, enrollees may report one of two possible ethnicities: either Hispanic/Latino or Not Hispanic. Enrollees may also choose to report one of five categories of race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White; "More Than One Race" may also be reported.

The NIH Guidelines on the Inclusion of Women and Minorities as Subjects of Clinical Research (updated October 1, 2001) and the earlier 1994 Guidelines require that, for NIH

supported Phase III clinical trials, studies must include analyses to detect significant differences in sex and minority subpopulations (subsets) except when prior studies do not support significant differences. Inclusion of subset analyses in all publications is strongly encouraged. If the analyses show no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice.

The 21st Century Cures Act of 2016 led to further updates in NIH policies, including the requirement beginning in 2017 that Phase III and other applicable clinical trials must report the results of analyses by sex, race, and ethnicity to ClinicalTrials.gov. Further, the NIH revised its Inclusion of Children policy in December 2017. This 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 at enrollment in annual progress reports, effective for applications, contracts, and intramural studies submitted on or after January 25, 2019.

As the lead federal organization conducting and supporting scientific research on infectious and immunologic diseases, NIAID carries out basic, applied, and clinical investigations within our intramural laboratories and provides extramural grant, cooperative agreement, and contract support to research scientists worldwide. NIAID continues to comply with the NIH policies regarding of inclusion of women and minorities, and their subpopulations, in clinical research.

## II. Strategies for Ensuring Compliance

### D. Peer Review

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 by NIH Scientific Review Officers (SROs) on reviewing the inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among women, and racial and ethnic groups. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the summary statement reporting the review results. 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 NIAID Council performs the second level of review and makes recommendations for funding to the NIAID Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NIAID. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

Effective January 2025, the new Simplified Framework for NIH Peer Review Criteria reorganizes peer review criteria into three central factors: importance. rigor and

feasibility, and expertise and resources. Inclusion criteria and coding and plans for valid design and analysis of Phase III clinical trials, previously evaluated under Additional Review Criteria, will be integrated within Factor 2 (Rigor and Feasibility). This change will help to emphasize the importance of these criteria in evaluating scientific merit.

The NIAID Scientific Review Program (SRP) conducts peer review of NIAID's contract proposals and grant applications that address Institute-specific needs. These typically include Solicited, NIAID-Requested Research, Research projects (R), Program Projects (P), Cooperative Agreements (U), Research Career Development Awards (K), institutional Training Grants (T), Conference Awards (R13 and U13), and Contracts (N01). Additionally, NIAID SRP conducts the initial peer review of applications submitted to four chartered review committees aligned separately with the Division of AIDS; Division of Microbiology and Infectious Diseases; and Division of Allergy, Immunology, and Transplantation. Identifies and recruits a broad pool of individual experts in scientific areas relevant to the NIAID mission to perform peer review of applications and proposals. Scientific review procedures have been instituted to ensure that program and grants staff review, monitor, and document adherence by the grantee with the Inclusion Guidelines. Procedures include the following:

SROs identify whether clinical research or clinical trials are proposed in applications and proposals under review, and whether any proposed trials are Phase I, II, or III. SROs provide guidance to reviewers regarding assessing acceptability of research procedures and compliance with NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research. Reviewers are also asked to evaluate whether the submission(s) include(s) the most appropriate age groups to conduct a clinical trial or research, considering the relevant scientific and ethical issues and the appropriateness of the justification for including or excluding specific groups. Assessment of these issues can affect a grant application's overall impact score.

Following the review of grant applications, SROs record the human subjects and inclusion of women, minorities, and individuals across the lifespan inclusion codes in IMPAC II and ensure the reviewers' assessment of acceptability or unacceptability for these issues is clearly documented in each Summary Statement, as well as their assessments of the Data and Safety Monitoring Plan for Phase I and Phase II clinical trials, and Data and Safety Monitoring Boards (DSMB) for Phase  multi-site clinical trials.

For contract proposals, the Technical Evaluation Report (TER) captures review information on clinical trials. The presence of a Phase III trial is indicated when relevant, and the TER captures reviewer assessment of human subject protections as well as information about inclusion of women, minorities, and individuals across the lifespan, which are rated as acceptable or unacceptable. However, the numerical score of a proposal can be affected by these factors only if the Technical Evaluation Criteria cover inclusion issues.

## E. 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, race and 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.

NIAID has developed a number of relevant standard operating procedures (SOPs) relating to oversight of NIAID-funded clinical trials and clinical research: (https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award-guidance-compliance, https://www.niaid.nih.gov/research/human-subjects-research-training-sop, https://www.niaid.nih.gov/research/grants-bar-awards-human-subjects, https://www.niaid.nih.gov/research/children-research-policy, https://www.niaid.nih.gov/research/human-subjects-certifications-irb-or-iec-sop) .

## F. Intramural

All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent. These plans are considered during the scientific review process. With the annual scientific review and IRB review renewal, the investigator documents the number, sex, race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed and plan to increase recruitment reviewed by both the Institute and the pertinent IRB. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health (ORWH).

## G. IC Training Approaches

NIH created the Inclusion Learning Path for NIH program officials 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. This course sequence includes an overview of inclusion policies, how to address inclusion-related human subjects system (HSS) warnings and errors, program official oversight and inclusion monitoring. More advanced training involves inclusion in Phase III clinical trials, contract data entry and understanding HSS reports.

The NIAID Division of Extramural Activities (DEA) sponsored the Extramural Policy Grand Rounds that includes updates on clinical research policy and inclusion issues, including the implementation of the Inclusion Across the Lifespan policy. This training and policy update was provided twice each year in FY 2022-2024. All extramural staff are invited to these sessions and have access to the archived training.

The NIAID Grants Management Program (GMP) provides twice yearly "Bumps in the Roads" trainings for extramural staff involving extramural policy topics impacting extramural grants and cooperative agreements, including any changes in grants policies and procedures associated with clinical research and inclusions. All extramural staff are invited and have access to the archived training.

The NIAID DEA also established an Extramural Staff Trainings resource page for program officials and DEA staff involved in extramural grants, cooperative agreements, contracts and peer review. This recently developed resource site provides a central repository of NIAID extramural staff trainings, including those that cover clinical research and inclusion concerns, for download or viewing.

In 2023, the NIAID DEA Office of Knowledge and Educational Resources published a refresher article for program officials on NIH inclusion policies and practices in the NIAID *Inside Extramural* staff newsletter. The article covered NIH and NIAID online resources for staff, exemptions from inclusion policy data and technical changes within the HSS impacting inclusion monitoring and provided contact information for NIAID inclusion coordinators within each scientific division.

## III. Analysis and Interpretation of Data

Aggregate data for FY 2022–2024 were provided by Office of Extramural Research through the HSS utilizing the current NIH dataset. The HSS database is the centralized repository for collecting and storing data for all NIH Institutes and Centers (ICs) on human subjects and clinical trials. These data can be captured electronically on the Human Subjects and Clinical Trial Information form and for reporting on their Research Performance Progress Report (RPPR) in non-competing years. The HSS provides the tools that allow NIH staff to better monitor and manage the data.

All study and enrollment data for FY 2022-2024 are shown in Tables 1 through 5 in the appendix section of this report.

### A. Enrollment for All NIH-Defined Clinical Research, by Sex, Race, and Ethnicity

The appended tables show enrollment data for FY 2022-2024. Table 1 provides the NIAID summary of aggregate enrollment data for extramural and intramural research protocols reported in FY 2022-2024, for sex by race and ethnicity respectively. The combined aggregate data show that 599,312 females enrolled as research participants in FY 2022, constituting 45.4% percent of the total enrollment, and 857,914 females enrolled as research participants in FY 2023, constituting 49.2% percent of the total enrollment followed by a total of 715,909 females enrolled as research participants in FY 2024, constituting 49.3% of the total enrollment for that year. Total aggregate enrollment of males and females for both extramural and intramural clinical research were 1,320,941, 1,742,656 and 1,451,409for FY 2022-2024, respectively. (Table 2).

For FY 2022–2024 minorities comprised 54.2%, 61.0%, and 71.7%, respectively, (Table 2) of total enrollment. When the total enrollment increased in FY 2023 and 2024, a larger proportion of the increase included minority participants.

Table 3 provides U.S. site enrollment data for NIAID clinical research for sex by race and ethnicity for FY 2022-2024. The largest minority group was Black/African American at 17.0% for both females and males in FY 2022; 26.6% females and 22.9% males in FY 2023; and 14.1% females and 18.7% males in FY 2024. The smallest minority group was Native Hawaiian/Pacific Islander at 0.2% females and males from FY 2022-2024.

For all three years, NIAID has continued its support of including females and minorities in its clinical research studies as shown in the enrollment data in this report.

## B. Enrollment for All NIH-Defined Phase III Clinical Trials, by Sex, Race, and Ethnicity

Aggregate enrollment data for NIAID extramural and intramural NIH-defined Phase III protocols reported in FY 2022, 2023 and 2024 (Table 4) showed a large proportion of female participants in all years. In FY 2022-2024, females made up 46.9%, 48.6%, and 49.1%, respectively, of all enrollees in Phase III clinical trials. Minority populations enrolled in these studies at high rates with average enrollment for females ranging from 73.3% to 85.5% and men ranging from 70.8% to 78.4% in FY 2022-2024.

Aggregate total inclusion data enrollment records (IERs) for FY 2022-2024 individually, were 2,409, 2,489, and 2,342, respectively, (Table 5A) for all study records. These data for FY 2022-2024 represent a total of 123, 133, and 133 IERs, respectively, for the Institute's Phase III trials (Table 5B).

## C. Research, Condition, and Disease Categorization (RCDC) Report

In addition to carrying out its scientific mission, the NIH exemplifies and promotes the highest level of public accountability. The NIH Research Portfolio Online Reporting Tools (RePORT) website is used by NIH to inform the public of how tax dollars are being spent on biomedical research within the 27 ICs. RePORT includes reports from Research, Condition, Disease Categorization (RCDC). RCDC is a NIH-wide, computer-driven text-mining process that reports spending in more than 300 categories of diseases, conditions, or research areas. Inclusion enrollment data by RCDC category will be available on the NIH RCDC Inclusion Statistics Report website (https://report.nih.gov/RISR/#/) later but are available by request. These data will now be published annually at this website.

# Appendix

## Table 1: Total Enrollment: All NIH-Defined Clinical Research

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

| FY | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 334,159 | 55.8 | 599,312 | 45.4 | 2,291 | 0.4 | 73,851 | 12.3 | 193,406 | 32.3 | 2,496 | 0.4 |
| 2022 | Male | 336,400 | 50.7 | 663,989 | 50.3 | 3,148 | 0.5 | 83,620 | 12.6 | 161,457 | 24.3 | 2,637 | 0.4 |
| 2022 | Unknown | 45,670 | 79.2 | 57,640 | 4.4 | 499 | 0.9 | 2,485 | 4.3 | 5,520 | 9.6 | 126 | 0.2 |
| 2023 | Female | 549,798 | 64.1 | 857,914 | 49.2 | 5,410 | 0.6 | 82,099 | 9.6 | 395,549 | 46.1 | 2,480 | 0.3 |
| 2023 | Male | 500,298 | 58.3 | 857,739 | 49.2 | 6,093 | 0.7 | 102,673 | 12.0 | 293,325 | 34.2 | 2,721 | 0.3 |
| 2023 | Unknown | 13,299 | 49.3 | 27,003 | 1.5 | 63 | 0.2 | 4,447 | 16.5 | 3,353 | 12.4 | 21 | 0.1 |
| 2024 | Female | 512,953 | 71.7 | 715,909 | 49.3 | 4,885 | 0.7 | 103,996 | 14.5 | 321,821 | 45.0 | 859 | 0.1 |
| 2024 | Male | 519,160 | 72.4 | 717,441 | 49.4 | 4,964 | 0.7 | 145,690 | 20.3 | 276,259 | 38.5 | 1,170 | 0.2 |
| 2024 | Unknown | 8,124 | 45.0 | 18,059 | 1.2 | 63 | 0.3 | 4,775 | 26.4 | 2,376 | 13.2 | 7 | 0.0 |

| FY | Sex | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 262,194 | 43.7 | 17,964 | 3.0 | 47,110 | 7.9 | 488,562 | 81.5 | 60,006 | 10.0 | 50,744 |
| 2022 | Male | 328,590 | 49.5 | 25,567 | 3.9 | 58,970 | 8.9 | 523,824 | 78.9 | 84,638 | 12.7 | 55,527 |
| 2022 | Unknown | 1,927 | 3.3 | 4,783 | 8.3 | 42,300 | 73.4 | 9,521 | 16.5 | 37,278 | 64.7 | 10,841 |
| 2023 | Female | 300,813 | 35.1 | 22,178 | 2.6 | 49,385 | 5.8 | 744,507 | 86.8 | 61,416 | 7.2 | 51,991 |
| 2023 | Male | 357,786 | 41.7 | 31,917 | 3.7 | 63,224 | 7.4 | 705,373 | 82.2 | 95,872 | 11.2 | 56,494 |
| 2023 | Unknown | 3,042 | 11.3 | 4,554 | 16.9 | 11,523 | 42.7 | 9,887 | 36.6 | 5,419 | 20.1 | 11,697 |
| 2024 | Female | 225,633 | 31.5 | 20,450 | 2.9 | 38,265 | 5.3 | 612,023 | 85.5 | 78,041 | 10.9 | 25,845 |
| 2024 | Male | 217,443 | 30.3 | 21,090 | 2.9 | 50,825 | 7.1 | 592,102 | 82.5 | 91,840 | 12.8 | 33,499 |
| 2024 | Unknown | 2,986 | 16.5 | 237 | 1.3 | 7,615 | 42.2 | 9,466 | 52.4 | 881 | 4.9 | 7,712 |

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

# Table 2: Enrollment by Race

## Table 4-1-1-C. Total NIAID Enrollment: All NIH-Defined Clinical Research

| FY | Total Enrollment | No. Inclusion Data Records | Minority Enrollment | % Minority Enrollment | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian |
|---|---|---|---|---|---|---|---|---|
| 2022 | 1,320,941 | 2,409 | 716,229 | 54.2 | 5,938 | 0.4 | 159,956 | 12.1 |
| 2023 | 1,742,656 | 2,489 | 1,063,395 | 61.0 | 11,566 | 0.7 | 189,219 | 10.9 |
| 2024 | 1,451,409 | 2,342 | 1,040,237 | 71.7 | 9,912 | 0.7 | 254,461 | 17.5 |

| FY | 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | 360,383 | 27.3 | 5,259 | 0.4 | 592,711 | 44.9 | 48,314 | 3.7 | 148,380 | 11.2 |
| 2023 | 692,227 | 39.7 | 5,222 | 0.3 | 661,641 | 38.0 | 58,649 | 3.4 | 124,132 | 7.1 |
| 2024 | 600,456 | 41.4 | 2,036 | 0.1 | 446,062 | 30.7 | 41,777 | 2.9 | 96,705 | 6.7 |

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

# Table 3: US Site Enrollment: All NIH-Defined Clinical Research

## Table 5-1-2-C. US Site Enrollment for NIAID: All NIH-Defined Extramural and Intramural Clinical Research, Sex by Race and Ethnicity

| FY | Sex | Minority | % Minority | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian | Black African American | % Black African American | Native Hawaiian Pacific Islander | % Native Hawaiian Pacific Islander |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 100,373 | 29.3 | 1,815 | 0.5 | 8,821 | 2.6 | 58,196 | 17.0 | 679 | 0.2 |
| 2022 | Male | 125,909 | 29.6 | 2,174 | 0.5 | 9,780 | 2.3 | 72,257 | 17.0 | 1,038 | 0.2 |
| 2022 | Unknown | 626 | 6.8 | 18 | 0.2 | 45 | 0.5 | 234 | 2.5 | 46 | 0.5 |
| 2023 | Female | 182,691 | 38.6 | 2,769 | 0.6 | 12,388 | 2.6 | 126,058 | 26.6 | 742 | 0.2 |
| 2023 | Male | 190,749 | 36.1 | 2,994 | 0.6 | 13,739 | 2.6 | 121,115 | 22.9 | 1,174 | 0.2 |
| 2023 | Unknown | 1,386 | 13.5 | 61 | 0.6 | 215 | 2.1 | 418 | 4.1 | 7 | 0.1 |
| 2024 | Female | 109,336 | 36.5 | 2,290 | 0.8 | 11,363 | 3.8 | 42,278 | 14.1 | 520 | 0.2 |
| 2024 | Male | 127,639 | 41.2 | 2,202 | 0.7 | 11,136 | 3.6 | 57,954 | 18.7 | 769 | 0.2 |
| 2024 | Unknown | 1,335 | 13.3 | 61 | 0.6 | 208 | 2.1 | 512 | 5.1 | 7 | 0.1 |

| FY | Sex | 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 | 242,394 | 70.6 | 7,029 | 2.0 | 24,201 | 7.1 | 287,014 | 83.6 | 27,573 | 8.0 | 28,548 | 8.3 |
| 2022 | Male | 300,285 | 70.7 | 6,973 | 1.6 | 32,195 | 7.6 | 353,933 | 83.3 | 38,150 | 9.0 | 32,619 | 7.7 |
| 2022 | Unknown | 545 | 5.9 | 61 | 0.7 | 8,307 | 89.7 | 631 | 6.8 | 255 | 2.8 | 8,370 | 90.4 |
| 2023 | Female | 289,290 | 61.1 | 11,783 | 2.5 | 30,282 | 6.4 | 403,967 | 85.3 | 34,732 | 7.3 | 34,613 | 7.3 |
| 2023 | Male | 337,628 | 63.9 | 11,934 | 2.3 | 40,103 | 7.6 | 437,670 | 82.8 | 47,759 | 9.0 | 43,258 | 8.2 |
| 2023 | Unknown | 2,316 | 22.6 | 167 | 1.6 | 7,048 | 68.9 | 2,531 | 24.7 | 625 | 6.1 | 7,076 | 69.2 |
| 2024 | Female | 206,659 | 69.1 | 9,931 | 3.3 | 26,212 | 8.8 | 244,467 | 81.7 | 46,267 | 15.5 | 8,519 | 2.8 |
| 2024 | Male | 193,001 | 62.3 | 7,162 | 2.3 | 37,347 | 12.1 | 234,988 | 75.9 | 53,155 | 17.2 | 21,428 | 6.9 |
| 2024 | Unknown | 2,257 | 22.5 | 203 | 2.0 | 6,798 | 67.7 | 2,871 | 28.6 | 460 | 4.6 | 6,715 | 66.8 |

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

# Table 4: All Enrollment: All NIH-Defined Clinical Research

## Table 5-2-2-C. All Enrollment for NIAID: All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

| FY | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 41,853 | 73.3 | 57,060 | 46.9 | 709 | 1.2 | 3,378 | 5.9 | 24,226 | 42.5 | 50 | 0.1 |
| 2022 | Male | 41,953 | 70.8 | 59,272 | 48.7 | 1,034 | 1.7 | 5,193 | 8.8 | 15,472 | 26.1 | 103 | 0.2 |
| 2022 | Unknown | 4,838 | 91.9 | 5,267 | 4.3 | 3 | 0.1 | 215 | 4.1 | 4,391 | 83.4 | 0 | 0.0 |
| 2023 | Female | 61,509 | 76.8 | 80,080 | 48.6 | 2,780 | 3.5 | 7,239 | 9.0 | 40,554 | 50.6 | 61 | 0.1 |
| 2023 | Male | 61,217 | 74.1 | 82,606 | 50.1 | 3,097 | 3.7 | 14,669 | 17.8 | 24,246 | 29.4 | 134 | 0.2 |
| 2023 | Unknown | 822 | 37.3 | 2,204 | 1.3 | 10 | 0.5 | 220 | 10.0 | 322 | 14.6 | 0 | 0.0 |
| 2024 | Female | 61,120 | 85.5 | 71,463 | 49.1 | 2,757 | 3.9 | 6,550 | 9.2 | 42,037 | 58.8 | 52 | 0.1 |
| 2024 | Male | 57,180 | 78.4 | 72,924 | 50.1 | 3,078 | 4.2 | 10,710 | 14.7 | 24,825 | 34.0 | 131 | 0.2 |
| 2024 | Unknown | 789 | 70.5 | 1,119 | 0.8 | 10 | 0.9 | 223 | 19.9 | 328 | 29.3 | 2 | 0.2 |

| FY | Sex | 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 | 19,475 | 34.1 | 5,116 | 9.0 | 4,106 | 7.2 | 38,786 | 68.0 | 14,042 | 24.6 | 4,232 | 7.4 |
| 2022 | Male | 24,175 | 40.8 | 7,224 | 12.2 | 6,071 | 10.2 | 34,549 | 58.3 | 21,104 | 35.6 | 3,619 | 6.1 |
| 2022 | Unknown | 146 | 2.8 | 1 | 0.0 | 511 | 9.7 | 4,645 | 88.2 | 260 | 4.9 | 362 | 6.9 |
| 2023 | Female | 23,192 | 29.0 | 1,455 | 1.8 | 4,799 | 6.0 | 60,883 | 76.0 | 13,421 | 16.8 | 5,776 | 7.2 |
| 2023 | Male | 28,770 | 34.8 | 3,941 | 4.8 | 7,749 | 9.4 | 57,075 | 69.1 | 21,740 | 26.3 | 3,791 | 4.6 |
| 2023 | Unknown | 192 | 8.7 | 14 | 0.6 | 1,446 | 65.6 | 665 | 30.2 | 304 | 13.8 | 1,235 | 56.0 |
| 2024 | Female | 15,917 | 22.3 | 1,714 | 2.4 | 2,436 | 3.4 | 53,677 | 75.1 | 11,995 | 16.8 | 5,791 | 8.1 |
| 2024 | Male | 24,377 | 33.4 | 4,137 | 5.7 | 5,666 | 7.8 | 49,482 | 67.9 | 21,037 | 28.8 | 2,405 | 3.3 |
| 2024 | Unknown | 219 | 19.6 | 38 | 3.4 | 299 | 26.7 | 728 | 65.1 | 250 | 22.3 | 141 | 12.6 |

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

## Table 5A: Section 2: Metrics Based on Inclusion Data Records (IERs)

### Table 2-1. Total NIAID Inclusion Data Records (IERs): All NIH-Defined Extramural and Intramural Clinical Research Reported Between FY 2022 and 2024

| FY | 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 | 2,409 | 825 | 1,584 | 1,065 | 519 | 120 | 82 | 1,382 |
| 2023 | 2,489 | 804 | 1,685 | 1,136 | 549 | 143 | 77 | 1,465 |
| 2024 | 2,342 | 723 | 1,619 | 1,092 | 527 | 124 | 84 | 1,411 |

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

## Table 5B: Total Inclusion Data Records (IERs): All NIH-Defined Phase III Trials

**Table 2-2. Total NIAID Inclusion Data Records (IERs): All NIH-Defined Extramural and Intramural Phase III Trials Reported Between FY 2022 and 2024**

| FY | 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 | 123 | 20 | 103 | 66 | 37 | 6 | 5 | 92 |
| 2023 | 133 | 23 | 110 | 71 | 39 | 6 | 6 | 98 |
| 2024 | 133 | 23 | 110 | 70 | 40 | 5 | 7 | 98 |

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