# National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

## Triennial Report

## Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

### I. Background/Overview

The NIH and NIAMS are committed to the inclusion of women and minorities in all NIH-funded clinical research. As required by the NIH Revitalization Act of 1993 (Public Law 103-43), women and members of minority groups and their subpopulations as research participants must be included in all NIH-funded clinical research. Additionally, NIH-defined Phase III clinical trials must be carried out in a manner sufficient to analyze data by race, ethnicity, and sex and report these results in accordance with policy. The overall goal of the NIH Inclusion Policy is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study and the prevalence of the specific disease/condition in the population/ subpopulation.

#### A. Mission of the NIAMS

The mission of the NIAMS is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; the training of basic and clinical scientists to carry out this research; and the dissemination of information on research progress in these diseases. The NIAMS supports a multidisciplinary program of basic, clinical, and translational investigations; epidemiologic research; research centers; and research training for scientists within its own facilities as well as grantees at universities and medical schools nationwide. It also supports the dissemination of research results and information through the NIAMS Information Clearinghouse and through the NIH Osteoporosis and Related Bone Diseases National Resource Center.

#### B. Description of the NIAMS Clinical Research Portfolio

The Institute's research portfolio includes five core mission areas: Systemic Rheumatic and Autoimmune Diseases, Bone Biology and Diseases, Muscle Biology and Diseases, Joint Biology and Diseases and Orthopaedics, and Skin Biology and Diseases.

Under Systemic Rheumatic and Autoimmune Diseases research area, the NIAMS supports:

- Arthritis Biology Program
- Rheumatic Diseases Integrative Biology Research Program
- Scleroderma, Fibrosis, and Autoinflammatory Disease Program
- Systemic Autoimmune Disease Biology Program

Under Bone Biology and Diseases research area, the NIAMS supports:

- Bone Biology, Metabolic Bone Disorders, and Osteoporosis Program
- Clinical, Integrative Physiology and Rare Diseases of Bone Program

Under Muscle Biology and Diseases research program, the NIAMS supports:

- Muscle Development and Physiology Program
- Muscle Disorders and Therapies Program

Under Joint Biology, Diseases, and Orthopaedics research program, the NIAMS supports:

- Cartilage and Connective Tissue Program
- Clinical Osteoarthritis and Diagnostic Imaging Program
- Musculoskeletal Tissue Engineering and Regenerative Medicine Program
- Orthopaedic Implant Science Program
- Orthopaedic Research Program

Under Skin Biology and Diseases research program, the NIAMS supports:

- Epidermis, Dermis, and Skin Senses Program
- Skin Immunology and Diseases, Skin Microbiome Program
- Skin Repair, Pigmentation and Appendages, Vasculature/Lymphatic Systems Program

In support of its research program goals and objectives, the NIAMS funds an extensive portfolio of clinical research, which includes interventional studies (i.e., clinical trials) and observational studies varying in size and complexity. While some of the diseases covered by the NIAMS mission are rare – affecting only a few thousand people worldwide, most are chronic and common, and many causes lifelong pain, disability, or disfigurement. They affect people of all ages, racial and ethnic populations, and economic groups. Many affect women and minorities disproportionately — both in increased numbers and increased disease severity. For example, women with systemic lupus erythematosus (SLE) outnumber men nine to one. African American women are three times as likely to have SLE as are white women. SLE is also more common in Hispanic, Asian, and American Indian women. SLE risk genes have been identified on the X chromosome, which provides potential evidence for this autoimmune disease’s sex bias.

Rheumatoid arthritis, osteoporosis, and osteoarthritis (in people over 45 years of age) are also more prevalent among women, whereas certain forms of ankylosing spondylitis (inflammation of the joints in the spine) occur more frequently in men. Given what is known about the populations affected by NIAMS diseases, it is important to ensure that the funded science is appropriately including individuals of diverse racial and ethnic groups.

## II. Strategies for Ensuring Compliance in the Extramural Program

Strategies for ensuring compliance with the inclusion policy begins well before grant applications are received for peer review. In the funding opportunity announcement (FOA), specific language is included to support the inclusion of diverse populations in clinical studies. Any exclusion of a specific race/ethnicity, sex, or age group must be scientifically justified in the grant application. NIAMS scientific review, program, and grants management staff are aware of the NIH policies on inclusion based on sex, race/ethnicity, and age in clinical research. The NIAMS inclusion representative serves as a resource to answer questions about policy and compliance.

### A. Peer Review

The implementation of inclusion guidelines involves the participation of NIAMS review, program, clinical management, and grants management staff. Inclusion is first addressed during the peer review process. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion based on 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/ethnicity, and age. 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. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies.

Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the minutes of the review session. 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. NIAMS program officials discuss issues of non-compliance with applicants and advise them on how to resolve problems. The applicant then modifies the project or provides additional information to address reviewer concerns. These procedures ensure that NIAMS funds no application with unacceptable inclusion of women, minorities, and age groups. Program staff monitor enrollment in annual progress reports and provide consultation to investigators for enhancing outreach to specific populations as needed. 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. For NIH-defined Phase III clinical trials, program staff monitor the requirement for sex and race/ethnicity analyses in annual progress reports. The Clinical Management Team is involved with monitoring inclusion data within the Human Subjects System (HSS) and addressing any technical issues that arise. They also provide expertise in devising strategies to help studies that are not meeting their inclusion goals and keep up to date on all inclusion policies.

### C. NIAMS Training Approaches

NIAMS 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 conducted by the NIH Office of Extramural Research (OER). The purpose of this training was to train NIH program and review staff on the NIH inclusion policies and procedures for the inclusion of women, minorities, and individuals across the lifespan. Staff may access the archived trainings on the NIH staff intranet. New NIAMS staff may also attend the NIH Integrated Core Curriculum training, which provides an intensive overview of the grants process and covers topics including initiative development, application submission, scientific peer review, resources and tools, council and pre-award, and post-award.

NIAMS Clinical Management staff provides updates on inclusion processes and addresses frequently asked inclusion and HSS questions. The Clinical Management staff collaborates with extramural Program Officers and grants management staff.

### D. NIAMS Specific Procedures

Additionally, some NIAMS clinical research studies, specifically clinical trials have an additional level of oversight implemented through a NIAMS-appointed Data and Safety Monitoring Board (DSMB) or a NIAMS-appointed Safety Officer (SO) who pays special attention to the enrollment of participants and whether the researchers are meeting specified sex and race/ethnicity targets. If a study is falling behind on reaching its minority goals, the monitoring body will request a plan from the principal investigator (PI) to improve the study's outreach to a particular population. The NIAMS and the monitoring body also pay careful attention to PI requests to add or replace clinical study sites to ensure that a new recruitment site will contribute the appropriate patient population to reach the study's inclusion targets. PIs must provide the following information before additional sites will be approved:

- Description of the patient population pool/catchment area of the new site (3-4 sentences)
- Overall study target enrollment
- Target enrollment for new site
- Description of the expected minority population pool of the new site
- Target minority enrollment for new site

## III. Strategies for Ensuring Compliance for Intramural Research

NIAMS requires all intramural investigators conducting clinical research to provide plans for the appropriate inclusion of women and minorities, or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural Institutional Review Boards (IRB) review the research protocols for compliance with inclusion guidelines and conduct annual Continuing Reviews. With each annual review and renewal, the investigator documents the number, sex, race, and ethnicity of participants who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by the pertinent IRB. The Clinical Center's Office of Protocol Services coordinates annual reporting of participant demographic data to the Office of Extramural Research (OER) and the Office of Research on Women's Health. As part of a quadrennial review policy, any clinical protocols that are open for four years or more involve discussion among the Institute Clinical Director and the PIs to discuss the adequacy of enrollment goals and any issues related to meeting them. Additionally, the NIAMS Clinical Director and Clinical Operations Manager meet yearly with individual PIs to carefully review study progress regarding target enrollment.

## IV. Analysis and Interpretation of Data

The appended tables show the NIAMS inclusion enrollment data for extramural and intramural clinical research studies in fiscal years (FY) 2022 through 2024. Please note that data reflected for FY2022 incorrectly included two Inclusion Enrollment Records (IERs) in the reporting that contained existing datasets with enrollment data of 139,518 participants. For the purposes of reporting inclusion data, existing datasets are not counted. This error incorrectly inflated our FY2022 enrollment numbers; however, this was corrected, and data are reflected correctly for FY2023.

### A. NIAMS Aggregate Inclusion Enrollment Data

Clinical research studies report inclusion enrollment data, which are contained within IERs in the HSS. Depending on how the project record is set up for reporting inclusion, a study may have one or more IERs representing different study populations.

Table 2-1 (see Appendix 1) shows the number of IERs for NIAMS Extramural and Intramural clinical research projects that reported inclusion data between FY2022 and FY2024. Most records were from grants conducting research at U.S. (domestic) sites. IERs without enrollment indicate studies that have not recruited any participants. Female-only or male-only IERs indicate studies that were scientifically justified to recruit only a single-sex. The total number of records reporting inclusion data increased from FY2022 to FY2023, with an overall 3% increase in records reporting data between FY2022 (529 IERs) and FY2023 (545 IERs). The total number of records reporting inclusion data decreased from FY2023 (545 IER) to FY2024 (514 IER), with an overall 6% decrease in records reporting data between FY2023 and FY2024

The total enrollment for all NIAMS intramural and extramural Clinical Research by sex, race, and ethnicity is displayed in Table 5-1-1-C (see Appendix 2). The NIAMS total participant counts declined between FY2022 (28,627 females, 9,949 males) and FY2023 (8,164 females, 4,275 males). In FY2024, the NIAMS total participant enrollment remained consistent with FY2023 total enrollment counts. In FY2024, the NIAMS total participant enrollment was 8,534 females and 4,185 males. The percentage of males (25.9%) enrolled in clinical research in FY2023 increased from FY2022 (24.9%). The percentage of females enrolled in clinical research declined from the FY2023 count (33%) as compared to FY2024 (29.1%). The decrease in the number of participants may be attributed to more inclusion records or performing quality control checks to distinguish existing datasets from active participant inclusion enrollment reports.

The percentage of minority enrollment for NIAMS clinical research studies has slightly increased in female and male participants. In FY2022- FY2023, the percentage of minority enrollment for female participants increased from 29.2% to 33%. In FY2022-FY2023, the percentage of minority enrollment for men increased from 24.9% to 25.9%. In FY2024, the percentage of minority enrollment remained consistent, with a slight decline in enrollment of female (29.1%) and male (20.4%) participants. The total enrollment by race and ethnicity showed some slight changes during FY2022 and FY2024. In FY2022-FY2024, the total enrollment percentages remained unchanged for the American Indian (0.4%) and Native Hawaiian/Pacific Islander participants (0.2%). In FY2022-FY2024, the total enrollment percentage of Asian participants has increased from 4.9% to 7.2%. In FY2024, the total enrollment of Asian participants was 4.9%. In FY2023-FY2024, the total enrollment percentage of Black/African American participants slightly declined from 13.6% to 12.1%. In FY2023-FY2024, the total enrollment percentage of Hispanic/Latino enrollment slightly declined from 7.8% to 6.4%. The total enrollment by race and ethnicity shows slight declines in total participant enrollment in both male and female participant counts.

The total enrollment for NIH-wide intramural and extramural Clinical Research by sex, race, and ethnicity is displayed in Table 5-1-1-C (see Appendix 4). In FY2024, NIAMS has a slightly higher total enrollment percentage for female participants than the NIH (58.2% in FY2024 for NIAMS; 55.5% in FY2022 for NIH-wide). In FY2023, the percentage of NIAMS female participant enrollment (57.8%) was slightly higher than NIH-wide data (56.5%). In FY2023, the percentage of the total enrollment of male participants for NIAMS was slightly higher than the NIH total enrollment percentage (38.5% for NIAMS; 37.2% NIH-wide).

For minority enrollment, NIAMS has lower total enrollment percentages across all racial/ethnic minority categories. In FY2022, the NIAMS enrollment percentage for minorities (28%) was slightly lower than the NIH-wide percentage (30.6%). In FY2023, the NIAMS total enrollment percentage for minorities (30.3%) was slightly lower than the NIH-wide percentage (44%). In FY2024, the NIAMS total enrollment percentage for minorities (25.4%) was slightly lower than the NIH-wide percentage (43%). The NIH-wide total enrollment counts for minority participants have declined from FY2022 (15,579,474 female and 14,044,907 male) to FY2023 (3,328,616 female and 1,998,338 male). In FY2024, the NIH total enrollment counts continue to show a decline (3,621,570 female and 2,284,529) compared to FY2023.

## NIAMS supported NIH-Defined Phase III Trials

NIAMS supports NIH-defined Phase III clinical trials. NIAMS extramural currently supports two NIH-defined phase III clinical trials that require valid analyses by sex and race/ethnicity, which includes six IERs.

The total enrollment for all NIAMS-supported NIH-Defined Phase III Clinical Trials by sex, race, and ethnicity is displayed in Table 5-2-2-C (see Appendix 3). In FY2022-FY2023, the total enrollment number for NIH-defined phase III clinical trials has increased from FY2022 (122 female and 86 male participants) to FY2023 (826 female and 392 male participant enrollment). In FY2022-FY2023, the total female participant enrollment has increased from FY2022 (58.7%) to FY2023 (67.1%).

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

As of March 1, 2022, NIAMS clinical research inclusion enrollment data by RCDC category are available on the NIH RePORT website through this link: https://report.nih.gov/RISR/

## V. Additional information

# Appendix 1

Table 2-1. Total Inclusion Data Records (IERs) for NIAMS Extramural and Intramural Clinical Research Reported Between FY2022 and FY2024

| 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 | 529 | 216 | 313 | 302 | 11 | 38 | 16 | 259 |
| 2023 | 545 | 222 | 323 | 314 | 9 | 27 | 16 | 280 |
| 2024 | 514 | 204 | 310 | 298 | 12 | 28 | 17 | 265 |

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

# Appendix 2

Table 5-1-1-C. Enrollment for All NIAMS Extramural and Intramural Clinical Research, Sex by Race and Ethnicity

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 28,627 | 29.2 | 98,000 | 70.2 | 86,799 | 88.6 | 10,095 | 10.3 | 1,106 | 1.1 |
| 2022 | Male | 9,949 | 24.9 | 39,971 | 28.6 | 35,778 | 89.5 | 3,572 | 8.9 | 621 | 1.6 |
| 2022 | Unknown | 518 | 33.5 | 1,547 | 1.1 | 86 | 5.6 | 506 | 32.7 | 955 | 61.7 |
| 2023 | Female | 8,164 | 33.0 | 24,773 | 57.8 | 21,105 | 85.2 | 2,674 | 10.8 | 994 | 4.0 |
| 2023 | Male | 4,275 | 25.9 | 16,488 | 38.5 | 14,584 | 88.5 | 1,289 | 7.8 | 615 | 3.7 |
| 2023 | Unknown | 541 | 34.2 | 1,580 | 3.7 | 156 | 9.9 | 513 | 32.5 | 911 | 57.7 |
| 2024 | Female | 8,534 | 29.1 | 29,289 | 58.2 | 22,365 | 76.4 | 3,110 | 10.6 | 3,814 | 13.0 |
| 2024 | Male | 4,185 | 20.4 | 20,554 | 40.9 | 16,000 | 77.8 | 1,309 | 6.4 | 3,245 | 15.8 |
| 2024 | Unknown | 53 | 11.5 | 461 | 0.9 | 99 | 21.5 | 28 | 6.1 | 334 | 72.5 |

| Fiscal Year | Sex | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 147 | 0.2 | 4,377 | 4.5 | 13,593 | 13.9 | 73 | 0.1 | 67,993 | 69.4 | 1,587 | 1.6 | 10,230 | 10.4 |
| 2022 | Male | 101 | 0.3 | 2,442 | 6.1 | 3,674 | 9.2 | 50 | 0.1 | 29,310 | 73.3 | 455 | 1.1 | 3,939 | 9.9 |
| 2022 | Unknown | 5 | 0.3 | 1 | 0.1 | 4 | 0.3 | 0 | 0.0 | 59 | 3.8 | 2 | 0.1 | 1,476 | 95.4 |
| 2023 | Female | 94 | 0.4 | 1,741 | 7.0 | 3,357 | 13.6 | 42 | 0.2 | 17,058 | 68.9 | 783 | 3.2 | 1,698 | 6.9 |
| 2023 | Male | 69 | 0.4 | 1,327 | 8.0 | 1,402 | 8.5 | 28 | 0.2 | 12,230 | 74.2 | 378 | 2.3 | 1,054 | 6.4 |
| 2023 | Unknown | 3 | 0.2 | 12 | 0.8 | 7 | 0.4 | 0 | 0.0 | 53 | 3.4 | 11 | 0.7 | 1,494 | 94.6 |
| 2024 | Female | 122 | 0.4 | 1,424 | 4.9 | 3,554 | 12.1 | 32 | 0.1 | 18,975 | 64.8 | 765 | 2.6 | 4,417 | 15.1 |
| 2024 | Male | 82 | 0.4 | 1,011 | 4.9 | 1,594 | 7.8 | 36 | 0.2 | 14,195 | 69.1 | 359 | 1.7 | 3,277 | 15.9 |
| 2024 | Unknown | 1 | 0.2 | 8 | 1.7 | 8 | 1.7 | 1 | 0.2 | 78 | 16.9 | 11 | 2.4 | 354 | 76.8 |

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

# Appendix 3

Table 5-2-2-C. All Enrollment for NIAMS Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 52 | 42.6 | 122 | 58.7 | 98 | 80.3 | 8 | 6.6 | 16 | 13.1 |
| 2022 | Male | 22 | 25.6 | 86 | 41.3 | 76 | 88.4 | 4 | 4.7 | 6 | 7.0 |
| 2022 | Unknown | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2023 | Female | 224 | 27.1 | 826 | 67.1 | 745 | 90.2 | 45 | 5.4 | 36 | 4.4 |
| 2023 | Male | 73 | 18.6 | 392 | 31.8 | 349 | 89.0 | 19 | 4.8 | 24 | 6.1 |
| 2023 | Unknown | 2 | 15.4 | 13 | 1.1 | 9 | 69.2 | 1 | 7.7 | 3 | 23.1 |
| 2024 | Female | 65 | 64.4 | 101 | 86.3 | 41 | 40.6 | 60 | 59.4 | 0 | 0.0 |
| 2024 | Male | 16 | 100.0 | 16 | 13.7 | 0 | 0.0 | 16 | 100.0 | 0 | 0.0 |
| 2024 | Unknown | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |

| Fiscal Year | Sex | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 0 | 0.0 | 2 | 1.6 | 38 | 31.1 | 0 | 0.0 | 74 | 60.7 | 4 | 3.3 | 4 | 3.3 |
| 2022 | Male | 0 | 0.0 | 0 | 0.0 | 18 | 20.9 | 0 | 0.0 | 64 | 74.4 | 0 | 0.0 | 4 | 4.7 |
| 2022 | Unknown | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 2023 | Female | 2 | 0.2 | 13 | 1.6 | 148 | 17.9 | 2 | 0.2 | 620 | 75.1 | 25 | 3.0 | 16 | 1.9 |
| 2023 | Male | 2 | 0.5 | 5 | 1.3 | 42 | 10.7 | 0 | 0.0 | 320 | 81.6 | 11 | 2.8 | 12 | 3.1 |
| 2023 | Unknown | 1 | 7.7 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 7 | 53.8 | 1 | 7.7 | 4 | 30.8 |
| 2024 | Female | 1 | 1.0 | 1 | 1.0 | 3 | 3.0 | 0 | 0.0 | 37 | 36.6 | 59 | 58.4 | 0 | 0.0 |
| 2024 | Male | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 16 | 100.0 | 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 |

# Appendix 4

Table 5-1-1-C. Enrollment for All **NIH-Wide** Extramural and Intramural Clinical Research, Sex by Race and Ethnicity

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 15,579,474 | 31.2 | 50,007,156 | 51.5 | 46,265,802 | 92.5 | 3,351,087 | 6.7 | 390,267 | 0.8 |
| 2022 | Male | 14,044,907 | 30.0 | 46,853,626 | 48.2 | 43,208,368 | 92.2 | 3,307,386 | 7.1 | 337,872 | 0.7 |
| 2022 | Unknown | 69,350 | 23.0 | 301,270 | 0.3 | 47,219 | 15.7 | 45,383 | 15.1 | 208,668 | 69.3 |
| 2023 | Female | 3,328,616 | 48.1 | 6,926,655 | 56.5 | 5,251,212 | 75.8 | 902,305 | 13.0 | 773,138 | 11.2 |
| 2023 | Male | 1,998,338 | 43.9 | 4,556,310 | 37.2 | 3,716,954 | 81.6 | 510,337 | 11.2 | 329,019 | 7.2 |
| 2023 | Unknown | 67,271 | 8.7 | 775,876 | 6.3 | 88,550 | 11.4 | 24,450 | 3.2 | 662,876 | 85.4 |
| 2024 | Female | 3,621,570 | 46.9 | 7,717,790 | 55.5 | 5,467,385 | 70.8 | 1,022,405 | 13.2 | 1,228,000 | 15.9 |
| 2024 | Male | 2,284,529 | 44.4 | 5,142,867 | 37.0 | 3,766,124 | 73.2 | 611,026 | 11.9 | 765,717 | 14.9 |
| 2024 | Unknown | 75,369 | 7.1 | 1,055,128 | 7.6 | 114,031 | 10.8 | 22,105 | 2.1 | 918,992 | 87.1 |

| Fiscal Year | Sex | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 592,947 | 1.2 | 1,537,559 | 3.1 | 9,358,983 | 18.7 | 64,156 | 0.1 | 36,701,652 | 73.4 | 1,204,269 | 2.4 | 547,590 | 1.1 |
| 2022 | Male | 579,925 | 1.2 | 1,386,168 | 3.0 | 8,089,658 | 17.3 | 64,887 | 0.1 | 35,167,186 | 75.1 | 1,144,408 | 2.4 | 421,394 | 0.9 |
| 2022 | Unknown | 1,118 | 0.4 | 9,982 | 3.3 | 11,792 | 3.9 | 262 | 0.1 | 17,673 | 5.9 | 6,857 | 2.3 | 253,586 | 84.2 |
| 2023 | Female | 235,723 | 3.4 | 824,640 | 11.9 | 1,441,191 | 20.8 | 24,338 | 0.4 | 3,158,527 | 45.6 | 184,424 | 2.7 | 1,057,812 | 15.3 |
| 2023 | Male | 103,586 | 2.3 | 544,257 | 11.9 | 847,196 | 18.6 | 17,416 | 0.4 | 2,389,426 | 52.4 | 120,362 | 2.6 | 534,067 | 11.7 |
| 2023 | Unknown | 2,896 | 0.4 | 12,616 | 1.6 | 19,733 | 2.5 | 547 | 0.1 | 57,867 | 7.5 | 13,106 | 1.7 | 669,111 | 86.2 |
| 2024 | Female | 92,322 | 1.2 | 831,033 | 10.8 | 1,525,881 | 19.8 | 24,660 | 0.3 | 3,669,170 | 47.5 | 292,481 | 3.8 | 1,282,243 | 16.6 |
| 2024 | Male | 60,332 | 1.2 | 611,423 | 11.9 | 918,924 | 17.9 | 18,257 | 0.4 | 2,667,198 | 51.9 | 174,014 | 3.4 | 692,719 | 13.5 |
| 2024 | Unknown | 4,385 | 0.4 | 19,520 | 1.9 | 18,288 | 1.7 | 751 | 0.1 | 81,907 | 7.8 | 12,302 | 1.2 | 917,975 | 87.0 |