


2025 Triennial NIDA Advisory Council Report for Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

I. Background/Overview

This report is on the inclusion of women and minorities in clinical research for FY2022-2024.

The NIH is mandated by the [Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2](#)  to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

The National Institute on Drug Abuse (NIDA) is the lead federal agency supporting scientific research on drug use and its consequences. The mission of NIDA is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health. This involves:

- Strategically supporting and conducting basic and clinical research on drug use (including nicotine), its consequences, and the underlying neurobiological, behavioral, and social mechanisms involved.
- Ensuring the effective translation, implementation, and dissemination of scientific research findings to improve the prevention and treatment of substance use disorders and enhance public awareness of addiction as a brain disorder.

NIDA has a broad portfolio of grants and contracts with human subjects that fall under the Inclusion of Women and Minorities Policy. The portfolio includes basic and clinical neuroscience, epidemiology, services, prevention, pharmacotherapies, medical consequences, treatment development, HIV/AIDS, as well as NIH defined phase III clinical trials. These efforts are coordinated by the NIDA Intramural and Extramural programs. When it comes to clinical and epidemiological study populations, NIDA's research has always been broad: Its portfolio by default addresses racial and/or ethnic minority groups who, unfortunately, may be disproportionately affected by consequences and problems related to drug use, including health problems such as HIV/AIDS.

In 1986 NIH established a policy for the inclusion of women in clinical research. This policy stemmed largely from a report of the Public Health Service Task Force on Women's Health in 1985. The policy was initially published in the NIH Guide to Grants and Contracts in 1987 and then later that year the policy was revised to include language encouraging the inclusion of minorities in clinical studies as well.

To ensure that NIH rigorously implement and enforce the inclusion policy, Congress included in The NIH Revitalization Act of 1993 (Public Law 103-43) a section entitled *Women and Minorities as Subjects in Clinical Research*. In 1994, NIH revised its policy to harmonize it with the statutory language. The policy, NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research, can be found at <https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/guideline>.

II. Strategies for Ensuring Compliance

NIDA supports the inclusion of a broad population in clinical studies. Funding announcements contain language requiring that women and racial and/or ethnic minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed. Applicants are encouraged to describe plans to collaborate with other centers to leverage resources for participant diversity and to set specific goals for inclusion of populations with health disparities. NIDA ensures that all applicants, peer reviewers, NIDA scientific review officers, program officers and grants management officers and specialists are aware of the NIH policies on inclusion based on sex, race, ethnicity, and age in clinical research.

A. 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](#) 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, 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. 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 NIDA Advisory Council performs the second level of review and makes recommendations for funding to the NIDA Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NIDA. 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 reorganized 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, are integrated within Factor 2 (Rigor and Feasibility). This change helps to emphasize the importance of these criteria in evaluating scientific merit.

B. Program Monitoring and Grants Management Oversight

NIDA ensures that applications are reviewed for compliance with the NIH Policy on Inclusion of Women and Minorities. 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 Grant Award, and that this information is appropriately documented in the official grant file.

C. NIDA's Training Approaches

Training at NIDA is a continual process. The NIDA inclusion representatives meet with program staff as needed to ensure compliance with NIH guidelines and to resolve technical issues related to maintaining these data for NIDA. NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for program staff, which are emphasized for new program staff and any existing staff that need refresher course work. Staff may access the training on the NIH staff intranet. Other training activities include the NIH Extramural Scientist Administrator (ESA) Core Curriculum which provides details on program official responsibilities for protection of human subjects.

D. 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 study participants who were accrued during the past year; any issues with accrual are addressed and plans to increase recruitment are 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).

III. Analysis and Interpretation of Data

Aggregate data for fiscal years (FY) 2022 through 2024 were provided by the NIH Office of Extramural Research (OER) through the Human Subjects System (HSS). 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.

NIDA's study and enrollment data by sex, race, and ethnicity for clinical research studies are shown in the attached tables. The total enrollment in FY2022 was 1,606,976; in FY2023 792,113; and in FY2024 607,816. A summary of the data showing the

percentage of racial and ethnic minority participants, Hispanic/Latino participants, and males and females, among all clinical research participants is provided here (with details in Tables 4-1-1-C Enrollment by Race, 4-1-1-D Enrollment by Ethnicity, 5-1-1-C Enrollment All Clinical Research at the end of this report):

| Fiscal Year | Minority (Clinical Research) | Hispanic/Latino | Male | Female | Unknown Sex |
|-------------|------------------------------|-----------------|------|--------|-------------|
| 2022 | 34.2 | 17.6 | 47.8 | 51.5 | 0.7 |
| 2023 | 40.3 | 13.7 | 48.9 | 49.5 | 1.6 |
| 2024 | 43.0 | 14.7 | 56.1 | 41.7 | 2.2 |

In Tables 2-1 and 2-2, the total inclusion enrollment records (IERs, also sometimes called inclusion data records, IDRs) capture the number of participants in clinical research studies and Phase III trials as reported by the study principal investigators in the applications. Table 2-3 includes the total IERs for Phase III trials that required a valid analysis by sex, and race and ethnicity. In FY2022, the total IERs for NIDA Phase III trials were 75, in FY2023 67, and in FY2024 57. The number of IERs that required valid analyses by sex, and race and ethnicity were 73 in FY2022, 67 in FY2023, and 57 in FY2024. These data are broken down further by sex, and race and ethnicity, and in Table 5-1-1-C.

Aggregate enrollment data for clinical research excluding male-only and female-only IERs are shown in Table 3-1-A respectively. In FY2022, 51.3% were female and 47.6% were male. In FY2023, 49.1% were female and 48.4% were male. In FY2024, 41.0% were female and 55.6% were male.

Table 4-2-1-C shows the minority enrollment data for all Phase III trials as 60.7% in FY2022, 54.6% in FY2023, and 59.3% in FY2024.

Aggregate enrollment data for NIDA Phase III trials excluding male-only and female-only IDRs are shown in Table 3-3 respectively. In FY2022, 35.1% were female and 63.3% were male. In FY2023, 36.4% were female and 62.3% were male. In FY2024, 40.3% were female and 49.5% were male.

Participants enrolled in NIDA Phase III trials are shown in Table 5-2-2-C. In FY2022, the data indicate that total enrollment was 36.2% female, 63.4% male, and 0.4% unknown

sex. 55.6% of female participants enrolled, 64% of male participants, and 0% of participants of unknown sex were from ethnic and racial minority groups.

In FY2023, the data indicate that total enrollment was 36.9% female, 62.7% male, and 0.4% unknown sex. 49.4% of female participants enrolled, 57.8% of male participants, and 27.1% of participants of unknown sex were from ethnic and racial minority groups.

In FY2024, the data indicate that total enrollment was 42.1% female, 57.2% male, and 0.7% unknown sex. 51.0% of female participants enrolled, 65.5% of male participants, and 44.1% of participants of unknown sex were from ethnic and racial minority groups.

For original reports and additional details about different ethnic and racial categories please see appendix tables.

NIDA validates and cleans the data to ensure the accuracy of datasets. The data presented are for studies between FY2022 - FY2024. Please note that the difference in total enrollment data between the years FY2022 and FY2023 is largely due to a single study reporting a large number of participants from a health system in FY2022. The study has ended. The difference in total enrollment data between years FY2023 and FY2024 for Phase III trials of Hispanic/Latino participants is due to studies ending in FY2023.

Research, Condition, and Disease Categorization (RCDC) Report

The RCDC Report is used by NIH to inform the public of how tax dollars are being spent to support biomedical research within the 27 institutes and centers. RCDC is a computerized process that reports more than 280 categories of diseases, conditions, or research areas. Inclusion enrollment data by 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.

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 | 1,535 | 781 | 754 | 725 | 29 | 63 | 33 | 658 |
| 2023 | 1,586 | 801 | 785 | 754 | 31 | 79 | 36 | 670 |
| 2024 | 1,676 | 817 | 859 | 825 | 34 | 108 | 28 | 723 |

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

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 | 75 | 33 | 42 | 40 | 2 | 12 | 2 | 28 |
| 2023 | 67 | 28 | 39 | 36 | 3 | 9 | 3 | 27 |
| 2024 | 57 | 25 | 32 | 27 | 5 | 9 | 1 | 22 |

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

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 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 | 75 | 73 | 97.3 | 73 | 97.3 |
| 2023 | 67 | 67 | 100.0 | 67 | 100.0 |
| 2024 | 57 | 57 | 100.0 | 57 | 100.0 |

Metrics Based on Aggregate Enrollment: Sex

Table 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 | 1,606,976 | 827,800 | 51.5 | 768,253 | 47.8 | 10,923 | 0.7 | 3,604 | 0.2 | 3,081 | 0.2 | 824,196 | 51.3 | 765,172 | 47.6 |
| 2023 | 792,113 | 391,992 | 49.5 | 387,305 | 48.9 | 12,816 | 1.6 | 3,404 | 0.4 | 3,664 | 0.5 | 388,588 | 49.1 | 383,641 | 48.4 |
| 2024 | 607,816 | 253,685 | 41.7 | 340,944 | 56.1 | 13,187 | 2.2 | 4,209 | 0.7 | 3,116 | 0.5 | 249,476 | 41.0 | 337,828 | 55.6 |

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 3-1-B. Total Enrollment for All NIH-Defined Extramural 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 | 1,600,182 | 824,596 | 51.5 | 764,701 | 47.8 | 10,885 | 0.7 | 3,604 | 0.2 | 3,081 | 0.2 | 820,992 | 51.3 | 761,620 | 47.6 |
| 2023 | 785,196 | 388,736 | 49.5 | 383,682 | 48.9 | 12,778 | 1.6 | 3,403 | 0.4 | 3,662 | 0.5 | 385,333 | 49.1 | 380,020 | 48.4 |
| 2024 | 599,570 | 249,726 | 41.7 | 336,711 | 56.2 | 13,133 | 2.2 | 4,209 | 0.7 | 3,116 | 0.5 | 245,517 | 40.9 | 333,595 | 55.6 |

Table 3-1-C. Total Enrollment for All NIH-Defined 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 | 6,794 | 3,204 | 47.2 | 3,552 | 52.3 | 38 | 0.6 | 0 | 0.0 | 0 | 0.0 | 3,204 | 47.2 | 3,552 | 52.3 |
| 2023 | 6,917 | 3,256 | 47.1 | 3,623 | 52.4 | 38 | 0.5 | 1 | 0.0 | 2 | 0.0 | 3,255 | 47.1 | 3,621 | 52.3 |
| 2024 | 8,246 | 3,959 | 48.0 | 4,233 | 51.3 | 54 | 0.7 | 0 | 0.0 | 0 | 0.0 | 3,959 | 48.0 | 4,233 | 51.3 |

Total Enrollment: All NIH-Defined Phase III Trials

Table 3-3. Total Enrollment for All NIH-Defined Phase III Trials Reporting 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 | 12,766 | 4,621 | 36.2 | 8,097 | 63.4 | 48 | 0.4 | 144 | 1.1 | 13 | 0.1 | 4,477 | 35.1 | 8,084 | 63.3 |
| 2023 | 12,751 | 4,707 | 36.9 | 7,996 | 62.7 | 48 | 0.4 | 64 | 0.5 | 57 | 0.4 | 4,643 | 36.4 | 7,939 | 62.3 |
| 2024 | 4,927 | 2,073 | 42.1 | 2,820 | 57.2 | 34 | 0.7 | 86 | 1.7 | 381 | 7.7 | 1,987 | 40.3 | 2,439 | 49.5 |

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

Enrollment by Race

Table 4-1-1-C. Total Enrollment of All NIH-Defined Clinical Research

| Fiscal Year | Total Enrollment | No. Inclusion Data Records | Minority Enrollment | % Minority Enrollment | 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 | 1,606,976 | 1,535 | 549,291 | 34.2 | 20,958 | 1.3 | 50,789 | 3.2 | 162,453 | 10.1 | 4,164 | 0.3 | 1,026,300 | 63.9 | 56,505 | 3.5 | 285,807 | 17.8 |
| 2023 | 792,113 | 1,586 | 319,430 | 40.3 | 15,993 | 2.0 | 26,407 | 3.3 | 157,484 | 19.9 | 1,632 | 0.2 | 428,322 | 54.1 | 18,946 | 2.4 | 143,329 | 18.1 |
| 2024 | 607,816 | 1,676 | 261,433 | 43.0 | 14,117 | 2.3 | 38,685 | 6.4 | 104,693 | 17.2 | 2,391 | 0.4 | 336,403 | 55.3 | 25,169 | 4.1 | 86,358 | 14.2 |

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

Enrollment by Ethnicity

Table 4-1-1-D. Total Enrollment of All NIH-Defined Clinical Research

| Fiscal Year | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|-------------|--------------|----------------|-----------------|-------------------|----------------------|------------------------|
| 2022 | 1,126,705 | 70.1 | 282,406 | 17.6 | 197,865 | 12.3 |
| 2023 | 639,690 | 80.8 | 108,264 | 13.7 | 44,159 | 5.6 |
| 2024 | 449,793 | 74.0 | 89,465 | 14.7 | 68,558 | 11.3 |

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 Phase III Trials Enrollment by Race

Table 4-2-1-C. Total Enrollment of All NIH-Defined Phase III Trials

| Fiscal Year | Total Enrollment | No. Inclusion Data Records | Minority Enrollment | % Minority Enrollment | 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 | 12,766 | 75 | 7,750 | 60.7 | 145 | 1.1 | 1,044 | 8.2 | 4,344 | 34.0 | 27 | 0.2 | 5,134 | 40.2 | 371 | 2.9 | 1,701 | 13.3 |
| 2023 | 12,751 | 67 | 6,965 | 54.6 | 195 | 1.5 | 273 | 2.1 | 3,939 | 30.9 | 27 | 0.2 | 6,091 | 47.8 | 227 | 1.8 | 1,999 | 15.7 |
| 2024 | 4,927 | 57 | 2,921 | 59.3 | 166 | 3.4 | 1,295 | 26.3 | 852 | 17.3 | 16 | 0.3 | 2,189 | 44.4 | 206 | 4.2 | 203 | 4.1 |

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 by Race and Ethnicity

| Fiscal Year | Sex | 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 |
|-------------|---------|------------------|---------|-------------------------------|---------------------------------|--------|---------|------------------------|--------------------------|----------------------------------|------------------------------------|---------|---------|--------------------|----------------------|----------------------|------------------------|
| 2022 | Female | 827,800 | 51.5 | 11,144 | 1.3 | 28,310 | 3.4 | 78,448 | 9.5 | 2,246 | 0.3 | 548,598 | 66.3 | 27,883 | 3.4 | 131,171 | 15.8 |
| 2022 | Male | 768,253 | 47.8 | 9,524 | 1.2 | 22,293 | 2.9 | 83,641 | 10.9 | 1,903 | 0.2 | 473,910 | 61.7 | 28,238 | 3.7 | 148,744 | 19.4 |
| 2022 | Unknown | 10,923 | 0.7 | 290 | 2.7 | 186 | 1.7 | 364 | 3.3 | 15 | 0.1 | 3,792 | 34.7 | 384 | 3.5 | 5,892 | 53.9 |
| 2023 | Female | 391,992 | 49.5 | 8,701 | 2.2 | 11,981 | 3.1 | 79,043 | 20.2 | 866 | 0.2 | 216,232 | 55.2 | 9,562 | 2.4 | 65,607 | 16.7 |
| 2023 | Male | 387,305 | 48.9 | 7,013 | 1.8 | 14,166 | 3.7 | 78,043 | 20.2 | 745 | 0.2 | 209,033 | 54.0 | 8,848 | 2.3 | 69,457 | 17.9 |
| 2023 | Unknown | 12,816 | 1.6 | 279 | 2.2 | 260 | 2.0 | 398 | 3.1 | 21 | 0.2 | 3,057 | 23.9 | 536 | 4.2 | 8,265 | 64.5 |
| 2024 | Female | 253,685 | 41.7 | 6,676 | 2.6 | 29,070 | 11.5 | 36,977 | 14.6 | 1,328 | 0.5 | 121,410 | 47.9 | 13,413 | 5.3 | 44,811 | 17.7 |
| 2024 | Male | 340,944 | 56.1 | 7,145 | 2.1 | 9,478 | 2.8 | 67,352 | 19.8 | 1,046 | 0.3 | 212,087 | 62.2 | 11,227 | 3.3 | 32,609 | 9.6 |
| 2024 | Unknown | 13,187 | 2.2 | 296 | 2.2 | 137 | 1.0 | 364 | 2.8 | 17 | 0.1 | 2,906 | 22.0 | 529 | 4.0 | 8,938 | 67.8 |

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|-------------|---------|----------|------------|------------------|---------|--------------|----------------|-----------------|-------------------|----------------------|------------------------|
| 2022 | Female | 288,277 | 34.8 | 827,800 | 51.5 | 589,975 | 71.3 | 155,277 | 18.8 | 82,548 | 10.0 |
| 2022 | Male | 259,196 | 33.7 | 768,253 | 47.8 | 532,053 | 69.3 | 126,330 | 16.4 | 109,870 | 14.3 |
| 2022 | Unknown | 1,818 | 16.6 | 10,923 | 0.7 | 4,677 | 42.8 | 799 | 7.3 | 5,447 | 49.9 |
| 2023 | Female | 162,479 | 41.4 | 391,992 | 49.5 | 317,148 | 80.9 | 56,720 | 14.5 | 18,124 | 4.6 |
| 2023 | Male | 154,920 | 40.0 | 387,305 | 48.9 | 316,433 | 81.7 | 50,726 | 13.1 | 20,146 | 5.2 |
| 2023 | Unknown | 2,031 | 15.8 | 12,816 | 1.6 | 6,109 | 47.7 | 818 | 6.4 | 5,889 | 46.0 |
| 2024 | Female | 132,339 | 52.2 | 253,685 | 41.7 | 155,870 | 61.4 | 51,222 | 20.2 | 46,593 | 18.4 |
| 2024 | Male | 127,247 | 37.3 | 340,944 | 56.1 | 290,012 | 85.1 | 37,449 | 11.0 | 13,483 | 4.0 |
| 2024 | Unknown | 1,847 | 14.0 | 13,187 | 2.2 | 3,911 | 29.7 | 794 | 6.0 | 8,482 | 64.3 |

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 by Race and Ethnicity

| Fiscal Year | Sex | 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 |
|-------------|---------|------------------|---------|-------------------------------|---------------------------------|-------|---------|------------------------|--------------------------|----------------------------------|------------------------------------|-------|---------|--------------------|----------------------|----------------------|------------------------|
| 2022 | Female | 4,621 | 36.2 | 63 | 1.4 | 222 | 4.8 | 1,535 | 33.2 | 15 | 0.3 | 2,125 | 46.0 | 186 | 4.0 | 475 | 10.3 |
| 2022 | Male | 8,097 | 63.4 | 82 | 1.0 | 822 | 10.2 | 2,809 | 34.7 | 12 | 0.1 | 3,006 | 37.1 | 185 | 2.3 | 1,181 | 14.6 |
| 2022 | Unknown | 48 | 0.4 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 3 | 6.3 | 0 | 0.0 | 45 | 93.8 |
| 2023 | Female | 4,707 | 36.9 | 91 | 1.9 | 100 | 2.1 | 1,202 | 25.5 | 11 | 0.2 | 2,552 | 54.2 | 106 | 2.3 | 645 | 13.7 |
| 2023 | Male | 7,996 | 62.7 | 104 | 1.3 | 170 | 2.1 | 2,732 | 34.2 | 16 | 0.2 | 3,525 | 44.1 | 119 | 1.5 | 1,330 | 16.6 |
| 2023 | Unknown | 48 | 0.4 | 0 | 0.0 | 3 | 6.3 | 5 | 10.4 | 0 | 0.0 | 14 | 29.2 | 2 | 4.2 | 24 | 50.0 |
| 2024 | Female | 2,073 | 42.1 | 74 | 3.6 | 402 | 19.4 | 294 | 14.2 | 8 | 0.4 | 1,113 | 53.7 | 99 | 4.8 | 83 | 4.0 |
| 2024 | Male | 2,820 | 57.2 | 86 | 3.0 | 892 | 31.6 | 553 | 19.6 | 8 | 0.3 | 1,062 | 37.7 | 107 | 3.8 | 112 | 4.0 |
| 2024 | Unknown | 34 | 0.7 | 6 | 17.6 | 1 | 2.9 | 5 | 14.7 | 0 | 0.0 | 14 | 41.2 | 0 | 0.0 | 8 | 23.5 |

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|-------------|---------|----------|------------|------------------|---------|--------------|----------------|-----------------|-------------------|----------------------|------------------------|
| 2022 | Female | 2,568 | 55.6 | 4,621 | 36.2 | 3,938 | 85.2 | 662 | 14.3 | 21 | 0.5 |
| 2022 | Male | 5,182 | 64.0 | 8,097 | 63.4 | 6,567 | 81.1 | 1,499 | 18.5 | 31 | 0.4 |
| 2022 | Unknown | 0 | 0.0 | 48 | 0.4 | 4 | 8.3 | 0 | 0.0 | 44 | 91.7 |
| 2023 | Female | 2,327 | 49.4 | 4,707 | 36.9 | 3,723 | 79.1 | 955 | 20.3 | 29 | 0.6 |
| 2023 | Male | 4,625 | 57.8 | 7,996 | 62.7 | 6,219 | 77.8 | 1,747 | 21.8 | 30 | 0.4 |
| 2023 | Unknown | 13 | 27.1 | 48 | 0.4 | 20 | 41.7 | 5 | 10.4 | 23 | 47.9 |
| 2024 | Female | 1,058 | 51.0 | 2,073 | 42.1 | 1,808 | 87.2 | 226 | 10.9 | 39 | 1.9 |
| 2024 | Male | 1,848 | 65.5 | 2,820 | 57.2 | 2,531 | 89.8 | 250 | 8.9 | 39 | 1.4 |
| 2024 | Unknown | 15 | 44.1 | 34 | 0.7 | 18 | 52.9 | 5 | 14.7 | 11 | 32.4 |

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