

## NATIONAL HUMAN GENOME RESEARCH INSTITUTE

### FY2022-FY2024 TRIENNIAL ADVISORY COUNCIL REPORT CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES

#### I. BACKGROUND AND OVERVIEW

The mission of the National Human Genome Research Institute (NHGRI) is to accelerate scientific and medical breakthroughs that improve human health by driving cutting-edge research, developing new technologies, and studying the impact of genomics on society. Since its inception in leading the Human Genome Project and completing the entire reference human genome in 2003, NHGRI has expanded its research portfolio from a narrow focus on studying the structure of the human genome. The broader scope includes funding research that strives to unravel the complexities of the human genome, identify the genomic underpinnings of human health and disease, and ensure that genomics is applied responsibly to improve patient care and benefit society. NHGRI's Intramural Research Program plans and conducts a broad program of laboratory and clinical research, and these efforts have elucidated and explored the biology and management of multiple genetic and other health conditions, including cancer; diabetes; premature aging; hereditary deafness; and various neurological, developmental, metabolic, and immunological disorders. The work of NHGRI Intramural Investigators also integrates social and behavioral research and genomics together with public health.

The NIH is mandated by the Public Health Service Act to ensure the inclusion of women<sup>1</sup> and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study. The primary goal of this law is to ensure that research findings can be generalizable to the entire population. Additionally, the statute requires clinical trials to be designed to provide information about differences by sex, race and/or ethnicity. Clinical research is defined as research with human subjects, including:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague)

---

<sup>1</sup> Pursuant to the Executive Order entitled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," the Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024 has been revised.

directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes:

- o Mechanisms of human disease
- o Therapeutic interventions
- o Clinical trials
- o Development of new technologies

2. Epidemiological and behavioral studies.

3. Outcomes research and health services research.

Not all studies involving human participants must be tracked. Most training, fellowship and career development awards do not require inclusion tracking. In addition, certain types of grants can be coded as exempt from tracking. This includes human subjects research that involves the collection or study of data or specimens that are publicly available, or recorded in such a way that subjects cannot be identified.

Inclusion coding and information is initially collected on the grant application using the PHS Human Subjects and Clinical Trials Information form. This form requires an Inclusion Enrollment Report (IER) for each study in the grant application. The IER table contains the planned distribution of subjects by sex, race, and ethnicity. Applicants also describe the rationale for selection of sex, racial, and ethnic group members in terms of the scientific objectives and proposed study design, as well as the proposed outreach for recruitment. Over the course of the grant as progress reports are submitted, the grantee submits IERs containing cumulative enrollment data, which is based on the actual number of participants recruited and examined in the course of the study.

Every three years, each NIH Institutional Advisory Council is required to review the aggregate data on the cumulative enrollment of participants in research supported by the Institute to ensure that the Institute: 1) is in compliance with the mandate for appropriate sex and minority inclusion; and 2) has in place adequate procedures to ensure these inclusion levels are monitored and maintained.

The following report discusses the aggregate enrollment data reported from FY2022 to FY2024 from the Extramural Research Program (ERP), including the Divisions of Genome Sciences, Genomic Medicine, and Genomics and Society, as well as the Intramural Research Program (IRP). This report also describes

the procedures followed by NHGRI staff to ensure appropriate sex and minority inclusion in all NHGRI research. The information contained in this report was reviewed by the National Advisory Council on Human Genome Research (NACHGR) and certified at the Council's closed session meeting of the February 2025 Council.

## II. STRATEGIES FOR ENSURING COMPLIANCE

### Extramural Research Program

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 the inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research applications. (Guidance document available at:

[https://grants.nih.gov/grants/peer/guidelines\\_general/Review\\_Human\\_Subjects\\_Inclusion.pdf](https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_Subjects_Inclusion.pdf).)

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. (See: <https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities/analyses>.) 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 NHGRI Advisory Council performs the second level of review and makes recommendations for funding to the NHGRI Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NHGRI. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

The ERP conducts an annual review of NHGRI's inclusion efforts and provides data to the NIH Office of Research on Women's Health. During the FY2022 to FY2024 reporting period, Ms. Christine Chang and Dr. Rongling Li served as the Institute's inclusion monitoring officers. They also provided guidance to extramural on inclusion policies and procedures. Staff have access to archived IC-specific training and

NIH-wide training (e.g., NIH Core Curriculum and Human Subjects System training at <https://era.nih.gov/help-tutorials/era-training-hss.htm>).

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.

### **Program Monitoring and Grants Management Oversight**

Prior to an award, 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. If a program director determines that the recruitment is behind schedule, s/he will contact the grantee to determine what measures can be taken to ensure that the recruitment goals are met within the specified time. For NIH-defined Phase III clinical trials, 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.

### **Intramural Research Program**

All new intramural clinical research studies require investigators to provide plans for the appropriate inclusion by sex, race, ethnicity, and age, and/or a justification whenever representation is limited or absent. These plans are considered during the initial scientific review process prior to Institutional Review Board (IRB) approval of the protocol. With the submission of the annual review for protocol renewal and quadrennial scientific reviews, the investigator documents the enrollment number, sex, race and ethnicity, including individual participant age-data as appropriate for the protocol, of those who were accrued during the past year. Issues with accrual are addressed and plans to modify recruitment may be reviewed scientifically by the Institute and the IRB. The Clinical Center's Protocol Services Section (PSS), formerly the Office of Protocol Services, coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health. Demographic participant data from NHGRI's Division of Intramural Research (DIR) for

this period were submitted by investigators to PSS for processing, and reviewed by the Office of the Clinical Director (OCD)/DIR in association with this report.

### **III. Analysis and Interpretation of Data from FY2022 to FY2024**

The clinical research studies funded by NHGRI tend to fall into a few basic categories: 1) qualitative studies that include a small number of research participants in focus group or structured interview settings; 2) phone, paper, or internet-based studies that survey the attitudes, beliefs or practices of either discrete populations (e.g., health professionals, genomic researchers, IRB chairs, individuals who have undergone genetic testing, disease/disability communities, minority communities) or the general population; 3) studies that utilize existing or prospectively identified cohorts for statistical analysis, prospective linkage/gene identification, or genome-wide associations; and 4) genomic medicine implementation studies that apply genetic testing/sequencing for clinical care. Some of the qualitative, survey, and genetic testing studies are limited to discrete target populations that may not always be racially or ethnically diverse. As a result, the demographic breakdown of NHGRI research enrollment may differ slightly from the U.S. population, depending on the types of studies active each year.

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 be published annually at this website.

Inclusion Enrollment Reports (IERs) contain study participant information for each grant or project. Because a single grant or project can have multiple studies, and each study can have multiple IERs, there can be multiple IERs per grant or project. For example, an extramural multicenter project will have multiple studies for different sites, and each study can also have multiple IERs to separate participants. 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 1 shows the total IERs for clinical research across NHGRI between FY2022 and FY2024. About a third of IERs did not have enrollment (36% in FY 2022, 30% in FY2023 and 35% in FY2024) because of delayed onset of recruitment or active studies that completed enrollment in previous years, eliminating the need for participant recruitment during the respective reporting year. Among the IERs with enrollment, the majority are associated with U.S. sites (96% in FY2022, 97% in FY2023 and 98% in

FY2024. Several studies each year include only women participants because of the nature of studies (e.g., pregnant women's views on prenatal sequencing) and three studies during this reporting period focused solely on men.

Table 2 shows actual enrollment and IERs by Extramural and Intramural Research Programs. The data spanning fiscal years 2022 to 2024 demonstrate a consistent increase in both participant enrollment and IERs for both programs, increasing from 28,467 participants and 186 IERs in the Extramural Research Program and 55,591 participants and 81 IERs in the Intramural Research Program. Although the Intramural Program has fewer IERs (29% of all NHGRI IERs), it is enrolling more participants (61% of study participants) compared to the Extramural Program. A consistency between this report and the previous triennial report is challenges with meeting annual, planned enrollment targets during and after the COVID-19 pandemic. In 2019, total enrollment was 250,151, dropping to 118,460 by 2021. By 2024, NHGRI enrolled 102,338 participants, indicating a meaningful increase but still significantly less than pre-pandemic enrollment. However, in the Intramural Research Program, a protocol with >32,000 participants closed following the FY2021 reporting period. The status-change of this one study is the primary driver for the apparent enrollment decline for intramural protocols comparing timeframes FY2019-FY2021 and FY2022-FY2024. Study enrollment since the COVID pandemic has otherwise been stable or improving for the intramural program.

### **Enrollment of Women**

NIH uses sex to indicate the enrollment of men and women in NIH clinical research. "Sex" refers to biological differences between women and men, including chromosomes, sex organs, and endogenous hormonal profiles. Table 3 shows sex distribution for all NHGRI protocols and while the actual number of women enrolled in NHGRI protocols decreased, since the previous report (largely due to the COVID-19 pandemic), the proportion of women represented in these protocols increased from FY2022 (53.3%) to FY2024 (58.6%), while enrollment of men remained steady at 40% between FY2022 and FY2024. By FY2024, there is also a reduction in the percentage of unknown sex (1.4%) possibly indicating improvement in sex identification and data quality.

### **Race and Ethnic Minority Distribution**

Race/ethnic (Table 4) minority distribution is shown with the following U.S. Census-designated race categories: American Indian/Alaska Native (AI/AN), Asian, Black/African American (B/AA), Native Hawaiian/Pacific Islander (AH/PI), White, More than One Race (MR), and Unknown/Not Reported

(UK/NR). When enrolling research participants, researchers ask participants to self-identify both their ethnicity and their race, with the option to select more than one racial category, or to decline providing race and ethnicity. Minority enrollment in this report includes all races except White and Unknown race, plus Hispanic enrollment not already identified in another race category that fits the minority definition.

The total proportion of minority enrollment increased between FY2022 (32.3%) to FY2023 (39.4%) to FY2024 (39.8%). This continues an upward trend that extends beyond the previous triennial report, as minority enrollment was at 25.0% in FY2017. The increased minority enrollment is due to efforts in both the Extramural and Intramural Programs to recruit minority participants.

Table 5 shows enrollment stratified by ethnicity, defined as Hispanic/Latino versus not Hispanic/Latino participants. Following the U.S. Office of Management and Budget's definition, Hispanic and Latino participants may be of any race. The proportion identifying as Hispanic/Latino increased from 7% in FY2022 to over 10% in FY2023 and FY2024.

#### **Race and Ethnicity Enrollment Distribution by Sex**

Table 6 shows enrollment for NHGRI clinical research parsed by sex, race, and ethnicity. It was noted above that the total proportion of minority enrollment has steadily increased since 2017. When stratified by sex, the increase in minority enrollment is greater among women participating in NHGRI protocols: FY2022 (46.4% minority among women vs. 42.0% among men), FY2023 (49.0% vs. 43.8%), and FY2024 (48.2% vs. 41.6%). There were no notable differences by sex in proportions identifying as Hispanic/Latino.

#### **Enrollment in Phase III Clinical Trials**

In previous years, NHGRI has not enrolled participants in phase III clinical trials, including FY2022 and FY2023 (Table 7). In FY2024, NHGRI supported one Phase III clinical trial, which was based in the United States. This study focused on advancing the integration of genomic medicine within an electronic health record (EHR) infrastructure across a diverse health system. The study's minority enrollment was lower than the overall minority participation in NHGRI-supported research. Specifically, 14.8% of women and 22.7% of men in this study identified as members of minority groups. However, women represented a higher proportion of participants in this trial, comprising 55.1% of the total enrollment. This aligns closely with the overall participation of women in NHGRI-funded research.

#### **IV. INCLUSION ACROSS THE LIFESPAN**

The NIH revised its Inclusion of Children Policy on December 19, 2017. The updated policy, now titled the *NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects*, extends to individuals of all ages. It mandates the reporting of participant age at the time of enrollment in annual progress reports. This policy is effective for applications submitted on or after January 25, 2019, as well as for contract solicitations and intramural studies that begin after this date.

Table 8 shows the age distribution for enrolled participants for FY2022 to FY2024 studies falling under this policy, which has been in place for six years and only applies to new studies. The age distribution of studies initiated prior to policy implementation are not included. Enrolled participants increased significantly in FY2023 and FY2024. The percentage of children in total participation remained relatively stable over the years. In FY2022, it was 7.7%, in FY2023 it dropped to 7.1%, and in FY2024, it increased to 8.7%. Adults aged 18-64 years represent the greatest proportion of study participants. Adults represented 55.6% of enrolled participants in FY2022, 76.8% in FY2023 and 69.6% in FY2024. The percentage of older adults has shown a notable increase, from 4.1% in FY2022 to 16.5% in FY2024. Conversely, the Unknown/Not Reported Data dropped from 32.6% in FY2022 to 5.1% in 2024, being the lowest at 3.8% in FY2023.

#### **V. CONCLUDING REMARKS**

Although total enrollment has increased in recent years, the impact of COVID-19 on NHGRI participant enrollment has continued to present significant challenges over the past three years. These challenges have led to ongoing delays and difficulties in reaching the planned target enrollment numbers. When reviewing the total enrollment across all NIH-defined clinical research supported by NHGRI (Table 4), there was a slight increase in the enrollment of racial and ethnic minorities, indicating overall maintenance of progress in diversity. Additionally, the proportion of women enrolled has grown, while male enrollment has remained steady. Notably, the proportion of participants with unknown or not reported data has decreased, reflecting improvements in data collection practices (Table 3). Overall, while progress has been made, continued efforts will be essential to address the residual effects of the pandemic and to ensure that efforts to maintain enrollment diversity and data completeness are continued.

**Table 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 | Women Only IERs | Men Only IERs | IERs Excluding Men only and Women only* |
|-------------|------------|-------------------------|----------------------|--------------|------------------|-----------------|---------------|-----------------------------------------|
| 2022        | 267        | 95                      | 172                  | 166          | 6                | 11              | 2             | 159                                     |
| 2023        | 277        | 82                      | 195                  | 189          | 6                | 15              | 1             | 179                                     |
| 2024        | 311        | 110                     | 201                  | 197          | 4                | 16              | 0             | 185                                     |

\*Inclusion Data Records (IERs) excluding men only and women only include unknown sex, and combination of unknown sex.

**Table 2. Participants and IERs by Extramural and Intramural for NIH-Defined Clinical Research Reported Between FY2022 and FY2024**

| Fiscal Year | Total             |             | Extramural        |             | Intramural        |             |
|-------------|-------------------|-------------|-------------------|-------------|-------------------|-------------|
|             | Actual Enrollment | No. of IERs | Actual Enrollment | No. of IERs | Actual Enrollment | No. of IERs |
| 2022        | 84,058            | 267         | 28,467            | 186         | 55,591            | 81          |
| 2023        | 96,558            | 277         | 38,967            | 195         | 57,591            | 82          |
| 2024        | 102,338           | 311         | 42,481            | 227         | 59,857            | 84          |

**Table 3. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2022 and 2024**

| Fiscal Year | Total Enrollment | Total Women | % Women | Total Men | % Men | Total Unknown | % Unknown |
|-------------|------------------|-------------|---------|-----------|-------|---------------|-----------|
| 2022        | 84,058           | 44,772      | 53.3    | 33,820    | 40.2  | 5,466         | 6.5       |
| 2023        | 96,558           | 52,822      | 54.7    | 38,373    | 39.7  | 5,363         | 5.6       |
| 2024        | 102,338          | 59,948      | 58.6    | 40,920    | 40.0  | 1,470         | 1.4       |

**Table 4. Minority Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2022 and FY2024**

| Fiscal Year | Total Enrollment | % Minority | % Minority | AI/AN | AI/AN | Asian | Asian | B/AA   | B/AA | NH/PI | NH/PI | White  | % White |
|-------------|------------------|------------|------------|-------|-------|-------|-------|--------|------|-------|-------|--------|---------|
| 2022        | 72,320           | 23,385     | 32.3       | 425   | 0.6   | 2,854 | 3.9   | 13,205 | 18.3 | 103   | 0.1   | 43,512 | 60.2    |
| 2023        | 88,353           | 34,794     | 39.4       | 485   | 0.5   | 3,149 | 3.6   | 19,624 | 22.2 | 118   | 0.1   | 48,729 | 55.2    |
| 2024        | 93,544           | 37,273     | 39.8       | 693   | 0.7   | 3,848 | 4.1   | 20,335 | 21.7 | 124   | 0.1   | 55,198 | 59.0    |

AI/AN: American Indian/Alaska Native, B/AA: Black/African American, NH/PI: Native Hawaiian/Pacific Islander

**Table 4 (cont'd). Minority Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2022 and FY2024**

| Fiscal Year | Total Enrollment | MR    | % MR | UK     | % UK |
|-------------|------------------|-------|------|--------|------|
| 2022        | 72,320           | 1,624 | 2.2  | 10,597 | 14.7 |
| 2023        | 88,353           | 2,395 | 2.7  | 13,853 | 15.7 |
| 2024        | 93,544           | 3,043 | 3.3  | 10,303 | 11.0 |

MR: More than One Race, UK: Unknown/Not Reported

**Table 5. Ethnic Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between FY2022 and FY2024**

| Fiscal Year | Not Hispanic |                | Hispanic        |                   | Unknown      |              | % Unknown |  |
|-------------|--------------|----------------|-----------------|-------------------|--------------|--------------|-----------|--|
|             | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Not Reported | Not Reported |           |  |
| 2022        | 68,141       | 81.1           | 5,889           | 7.0               | 10,028       |              | 11.9      |  |
| 2023        | 75,896       | 78.6           | 10,308          | 10.7              | 10,354       |              | 10.7      |  |
| 2024        | 82,856       | 81.0           | 10,423          | 10.2              | 9,059        |              | 8.9       |  |

**Table 6. Enrollment for All NIH-Defined Clinical Research by Sex, Race, and Ethnicity Reported Between Fiscal Years 2022 and 2024**

| Fiscal Year | Sex     | % Minority |          | Total Enrollment % |       | % AI/AN |       | % Asian |       | % B/AA |      | % NH/PI |       | % White |       |
|-------------|---------|------------|----------|--------------------|-------|---------|-------|---------|-------|--------|------|---------|-------|---------|-------|
|             |         | Minority   | Minority | Enrollment         | Total | AI/AN   | AI/AN | Asian   | Asian | B/AA   | B/AA | NH/PI   | NH/PI | White   | White |
| 2022        | Women   | 20,754     | 46.4     | 44,772             | 53.3  | 246     | 0.5   | 1,688   | 3.8   | 14,925 | 33.3 | 54      | 0.1   | 23,801  | 53.2  |
| 2022        | Men     | 14,198     | 42.0     | 33,820             | 40.2  | 175     | 0.5   | 1,445   | 4.3   | 9,631  | 28.5 | 48      | 0.1   | 19,493  | 57.6  |
| 2022        | Unknown | 136        | 2.5      | 5,466              | 6.5   | 4       | 0.1   | 16      | 0.3   | 57     | 1.0  | 1       | 0.0   | 218     | 4.0   |
| 2023        | Women   | 25,888     | 49.0     | 52,822             | 54.7  | 275     | 0.5   | 1,899   | 3.6   | 16,760 | 31.7 | 63      | 0.1   | 26,939  | 51.0  |
| 2023        | Men     | 16,823     | 43.8     | 38,373             | 39.7  | 202     | 0.5   | 1,524   | 4.0   | 10,570 | 27.5 | 54      | 0.1   | 21,591  | 56.3  |
| 2023        | Unknown | 138        | 2.6      | 5,363              | 5.6   | 8       | 0.1   | 21      | 0.4   | 54     | 1.0  | 1       | 0.0   | 199     | 3.7   |
| 2024        | Women   | 28,870     | 48.2     | 59,948             | 58.6  | 425     | 0.7   | 2,323   | 3.9   | 18,170 | 30.3 | 64      | 0.1   | 31,146  | 52.0  |
| 2024        | Men     | 17,024     | 41.6     | 40,920             | 40.0  | 252     | 0.6   | 1,794   | 4.4   | 10,599 | 25.9 | 60      | 0.1   | 23,676  | 57.9  |
| 2024        | Unknown | 161        | 11.0     | 1,470              | 1.4   | 16      | 1.1   | 26      | 1.8   | 53     | 3.6  | 0       | 0.0   | 376     | 25.6  |

AI/AN: American Indian/Alaska Native, B/AA: Black/African American, NH/PI: Native Hawaiian/Pacific Islander

**Table 6 (cont'd). Enrollment for All NIH-Defined Clinical Research by Sex, Race, and Ethnicity Reported Between Fiscal Years 2022 and 2024**

| Fiscal Year | Sex     | MR    | % MR | UK    | % UK |
|-------------|---------|-------|------|-------|------|
| 2022        | Women   | 947   | 2.1  | 3,111 | 6.9  |
| 2022        | Men     | 645   | 1.9  | 2,383 | 7.0  |
| 2022        | Unknown | 32    | 0.6  | 5,138 | 94.0 |
| 2023        | Women   | 1,584 | 3.0  | 5,302 | 10.0 |
| 2023        | Men     | 790   | 2.1  | 3,642 | 9.5  |
| 2023        | Unknown | 21    | 0.4  | 5,059 | 94.3 |
| 2024        | Women   | 1,980 | 3.3  | 5,840 | 9.7  |
| 2024        | Men     | 1,025 | 2.5  | 3,514 | 8.6  |
| 2024        | Unknown | 38    | 2.6  | 961   | 65.4 |

MR: More than One Race, UK: Unknown/Not Reported

**Table 6 (cont'd). Enrollment for All NIH-Defined Clinical Research by Sex, Race, and Ethnicity Reported Between Fiscal Years 2022 and 2024**

| Fiscal Year | Sex     | Not Hispanic |        | Hispanic |      | % Hispanic |      |
|-------------|---------|--------------|--------|----------|------|------------|------|
|             |         | Latino       | Latino | UK       | % UK |            |      |
| 2022        | Women   | 38,800       | 86.7   | 3,298    | 7.4  | 2,674      | 6.0  |
| 2022        | Men     | 28,860       | 85.3   | 2,561    | 7.6  | 2,399      | 7.1  |
| 2022        | Unknown | 481          | 8.8    | 30       | 0.5  | 4,955      | 90.7 |
| 2023        | Women   | 43,662       | 82.7   | 6,045    | 11.4 | 3,115      | 5.9  |
| 2023        | Men     | 31,692       | 82.6   | 4,218    | 11.0 | 2,463      | 6.4  |
| 2023        | Unknown | 542          | 10.1   | 45       | 0.8  | 4,776      | 89.1 |
| 2024        | Women   | 48,325       | 80.6   | 6,621    | 11.0 | 5,002      | 8.3  |
| 2024        | Men     | 33,794       | 82.6   | 3,763    | 9.2  | 3,363      | 8.2  |
| 2024        | Unknown | 737          | 50.1   | 39       | 2.7  | 694        | 47.2 |

UK: Unknown/Not Reported

**Table 7. Total Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research by Sex, Race, and Ethnicity Reported Between Fiscal Year 2024**

| Fiscal Year | Sex     | Minority | % Minority | Total Enrollment | % Total | AI/AN | % AI/AN | Asian | % Asian | B/AA | % B/AA | NH/PI | % NH/PI | White | % White |
|-------------|---------|----------|------------|------------------|---------|-------|---------|-------|---------|------|--------|-------|---------|-------|---------|
| 2024        | Women   | 8        | 14.8       | 54               | 55.1    | 0     | 0.0     | 5     | 9.3     | 3    | 5.6    | 0     | 0.0     | 40    | 74.1    |
| 2024        | Men     | 10       | 22.7       | 44               | 44.9    | 0     | 0.0     | 7     | 15.9    | 3    | 6.8    | 0     | 0.0     | 33    | 75.0    |
| 2024        | Unknown | 0        | 0.0        | 0                | 0.0     | 0     | 0.0     | 0     | 0.0     | 0    | 0.0    | 0     | 0.0     | 0     | 0.0     |

AI/AN: American Indian/Alaska Native, B/AA: Black/African American, NH/PI: Native Hawaiian/Pacific Islander

**Table 7 (cont'd). Total Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research by Sex, Race, and Ethnicity Reported Between Fiscal Year 2024**

| Fiscal Year | Sex     | MR | % MR | UK | % UK |
|-------------|---------|----|------|----|------|
| 2024        | Women   | 0  | 0.0  | 6  | 11.1 |
| 2024        | Men     | 0  | 0.0  | 1  | 2.3  |
| 2024        | Unknown | 0  | 0.0  | 0  | 0.0  |

MR: More than One Race, UK: Unknown/Not Reported

**Table 7 (cont'd). Total Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research by Sex, Race, and Ethnicity Reported Between Fiscal Years 2022 and 2024**

| Fiscal Year | Sex     | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | UK | % UK |
|-------------|---------|--------------|----------------|-----------------|-------------------|----|------|
| 2024        | Women   | 5            | 9.3            | 0               | 0.0               | 49 | 90.7 |
| 2024        | Men     | 7            | 15.9           | 0               | 0.0               | 37 | 84.1 |
| 2024        | Unknown | 0            | 0.0            | 0               | 0.0               | 0  | 0.0  |

UK: Unknown/Not Reported

**Table 8. Age Distribution for All NIH-Defined Clinical Research Reported Between Fiscal Years 2022 - 2024**

| Fiscal Year | Total  | Children (<18 years) | Adults (18-64 years) | Older Adults (65+ years) | Unknown or Not Reported |
|-------------|--------|----------------------|----------------------|--------------------------|-------------------------|
| 2022        | 9,186  | 704                  | 5,112                | 378                      | 2,992                   |
|             | 100%   | 7.7%                 | 55.6%                | 4.1%                     | 32.6%                   |
| 2023        | 28,101 | 1,988                | 21,586               | 3,451                    | 1,076                   |
|             | 100%   | 7.1%                 | 76.8%                | 12.3%                    | 3.8%                    |
| 2024        | 32,575 | 2,834                | 22,687               | 5,388                    | 1,666                   |
|             | 100%   | 8.7%                 | 69.6%                | 16.5%                    | 5.1%                    |