# The National Eye Institute (NEI) Report Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

## Background/Overview

Mission Statement of the NEI: As part of the Federal Government's National Institutes of Health (NIH), the National Eye Institute (NEI) was established to protect and prolong the vision of the American people. The National Eye Institute's mission is to eliminate vision loss and improve quality of life through vision research. To achieve this mission, NEI provides leadership to:

- Drive innovative research to understand the eye and visual system, prevent and treat vision diseases, and expand opportunities for people who are blind or require vision rehabilitation
- Foster collaboration in vision research and clinical care to develop new ideas and share knowledge across other fields
- Recruit, inspire, and train a talented and diverse new generation of individuals to expand and strengthen the vision workforce
- Educate health care providers, scientists, policymakers, and the public about advances in vision research and their impact on health and quality of life

Description of the NEI Portfolio: The NEI supports a significant number of clinical research projects on potentially blinding eye diseases and other visual disorders. Examples include diabetic retinopathy, amblyopia, age-related macular degeneration, glaucoma, retinopathy of prematurity, keratoconus, Fuchs endothelial corneal dystrophy, uveitis, retinitis pigmentosa, Leber's congenital amaurosis, cortical visual impairment, and myopia (nearsightedness).

## NEI Strategies for Ensuring Compliance

The Director, Division of Extramural Scientific Programs (DESP), NEI, is the official with responsibility for ensuring compliance. To educate the vision research community, inclusion policies are highlighted on the NEI extramural research website. The policy is also explicitly detailed in all NEI Notices of Funding Opportunity, Requests for Applications, and Requests for Proposals.

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 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 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. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

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. For NIH-defined Phase III clinical trials, program directors monitor the requirement for 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: 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, as part of their NIH protocol reviews. Intramural IRBs review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the investigator documents the number, sex, and race and ethnicity of those 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 (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health.

NEI Training Approaches: NEI staff are required to participate in the NIH Training on inclusion policies and procedures. The Director, DESP, routinely distributes policy updates to all staff. NEI staff members participate in several trans-NIH committees regularly involved with compliance and policy issues. All NEI-funded Phase III clinical trials are supported through the cooperative agreement mechanism. NEI Clinical Program Directors collaborate with the study team to ensure that all protocols are designed with appropriate inclusion goals before funding. Most Phase III trials are multicenter, which permits broader sampling of minority subpopulations. NEI staff monitor enrollment in all Phase III trials routinely and document inclusion in the grant file. NEI staff work collaboratively with study biostatisticians to ensure that appropriate valid analyses of differences in intervention effect are performed.

## Analysis and Interpretation of Data

The appended tables and graphs show enrollment data for fiscal years (FY) 2022-2024. Table 2-1 includes Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research. Approximately 95 percent of NEI studies include both females and males. The NEI has few female-only or male-only studies and most of these are studies that include samples derived from existing data sources. Tables 5-1-1-C and 5-2-2-C include Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity and Enrollment for Phase III studies respectively. These tables include data from large international studies in Nepal and in Ethiopia resulting in the appearance of a very large percentage of “Asian American” and “Black/African American” participants. Additional data is presented excluding these studies - see appended graphs (Figure 1-6). As shown in Figure1 and 2, women represented approximately 53.9 percent of enrolled participants for all clinical research and 51.9 percent in Phase III clinical trials. The NEI data showed good representation of racial and ethnic inclusion (Figure 3-6). Approximately 40 percent of the NEI data were from minority participants. NEI data appropriately reflect the make-up of the U.S. population.

Women study participants were well represented in NEI-sponsored Phase III clinical trials. Inclusion of minority groups in Phase III clinical trials was commensurate with United States population averages. Inclusion of Hispanic participants in Phase III clinical trials was commensurate with United States population averages as well. All NEI-funded Phase III clinical trials are designed with enrollment targets for sex, race, and ethnicity which result in sufficient power for valid subgroup analyses as required by policy.  Inclusion data broken out by Research, Condition, and Disease Categorization (RCDC) can be found at: https://report.nih.gov/RISR/.

Age data based on inclusion records showed a good distribution across the lifespan – see appended Figure 7. NEI studies include infants who have retinopathy of prematurity, young children with a variety of vision disorders including amblyopia, strabismus and myopia, and older participants with diseases such as diabetic retinopathy, macular degeneration, glaucoma, and cataracts.

The NEI supports a large portfolio of clinical research. The National Advisory Eye Council reviewed the inclusion data and concluded that the NEI has complied with the NIH Policy on Inclusion of Women & Minorities in Clinical Research. Overall, inclusion of minority groups in NEI clinical research was commensurate with United States population averages. NEI inclusion data is very positive in terms of scientific representation. This is important for generalizability of study results and critical for scientific value. The NEI should continue to strive for generalizability which will maintain the scientific value of vision science.

## Additional Information

The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities as Subjects in Clinical Research on November 28, 2017, to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised 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 age at enrollment in annual progress reports. The policy is effective for applications submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated after this date. The 21st Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Thus, this triennial report provides information on inclusion of participants in NEI clinical research from FY 2022 – 2024.

**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 | 541 | 185 | 356 | 326 | 30 | 6 | 16 | 334 |
| 2023 | 537 | 185 | 352 | 320 | 32 | 6 | 7 | 339 |
| 2024 | 468 | 172 | 296 | 276 | 20 | 8 | 7 | 281 |

**Total Enrollment: All NIH-Defined Clinical Research**

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

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian | Black African American | % Black African American | Native Hawaiian Pacific Islander | % Native Hawaiian Pacific Islander | White | % White | More Than One Race | % More Than One Race | Unknown Not Reported | % Unknown Not Reported | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 59,931 | 77.0 | 77,868 | 52.7 | 213 | 0.3 | 29,805 | 38.3 | 24,709 | 31.7 | 128 | 0.2 | 18,620 | 23.9 | 1,177 | 1.5 | 3,216 | 4.1 | 71,733 | 92.1 | 4,658 | 6.0 | 1,477 | 1.9 |
| 2022 | Male | 51,624 | 76.4 | 67,581 | 45.8 | 238 | 0.4 | 27,513 | 40.7 | 20,214 | 29.9 | 121 | 0.2 | 16,023 | 23.7 | 779 | 1.2 | 2,693 | 4.0 | 62,892 | 93.1 | 3,291 | 4.9 | 1,398 | 2.1 |
| 2022 | Unknown | 346 | 15.6 | 2,220 | 1.5 | 3 | 0.1 | 76 | 3.4 | 11 | 0.5 | 4 | 0.2 | 204 | 9.2 | 32 | 1.4 | 1,890 | 85.1 | 295 | 13.3 | 235 | 10.6 | 1,690 | 76.1 |
| 2023 | Female | 62,063 | 76.9 | 80,715 | 52.1 | 215 | 0.3 | 28,716 | 35.6 | 27,303 | 33.8 | 134 | 0.2 | 19,533 | 24.2 | 1,197 | 1.5 | 3,617 | 4.5 | 73,990 | 91.7 | 5,340 | 6.6 | 1,385 | 1.7 |
| 2023 | Male | 55,510 | 76.9 | 72,142 | 46.6 | 229 | 0.3 | 27,193 | 37.7 | 23,740 | 32.9 | 124 | 0.2 | 16,716 | 23.2 | 944 | 1.3 | 3,196 | 4.4 | 66,865 | 92.7 | 3,944 | 5.5 | 1,333 | 1.8 |
| 2023 | Unknown | 396 | 19.0 | 2,087 | 1.3 | 2 | 0.1 | 56 | 2.7 | 23 | 1.1 | 6 | 0.3 | 216 | 10.3 | 74 | 3.5 | 1,710 | 81.9 | 334 | 16.0 | 252 | 12.1 | 1,501 | 71.9 |
| 2024 | Female | 38,769 | 64.4 | 60,160 | 52.1 | 285 | 0.5 | 29,144 | 48.4 | 4,688 | 7.8 | 125 | 0.2 | 22,251 | 37.0 | 707 | 1.2 | 2,960 | 4.9 | 54,705 | 90.9 | 4,224 | 7.0 | 1,231 | 2.0 |
| 2024 | Male | 35,664 | 67.3 | 52,993 | 45.9 | 273 | 0.5 | 28,449 | 53.7 | 3,176 | 6.0 | 108 | 0.2 | 17,817 | 33.6 | 528 | 1.0 | 2,642 | 5.0 | 48,439 | 91.4 | 3,489 | 6.6 | 1,065 | 2.0 |
| 2024 | Unknown | 418 | 18.0 | 2,318 | 2.0 | 7 | 0.3 | 52 | 2.2 | 28 | 1.2 | 4 | 0.2 | 267 | 11.5 | 55 | 2.4 | 1,905 | 82.2 | 345 | 14.9 | 290 | 12.5 | 1,683 | 72.6 |

## All Enrollment: All NIH-Defined Clinical Research

**Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity**

| Fiscal Year | Sex | Minority | % Minority | Total Enrollment | % Total | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian | Black African American | % Black African American | Native Hawaiian Pacific Islander | % Native Hawaiian Pacific Islander | White | % White | More Than One Race | % More Than One Race | Unknown Not Reported | % Unknown Not Reported | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2022 | Female | 44,615 | 97.5 | 45,761 | 51.5 | 13 | 0.0 | 25,484 | 55.7 | 18,739 | 40.9 | 9 | 0.0 | 1,375 | 3.0 | 64 | 0.1 | 77 | 0.2 | 45,394 | 99.2 | 342 | 0.7 | 25 | 0.1 |
| 2022 | Male | 41,878 | 97.2 | 43,080 | 48.5 | 13 | 0.0 | 24,411 | 56.7 | 17,052 | 39.6 | 6 | 0.0 | 1,458 | 3.4 | 48 | 0.1 | 92 | 0.2 | 42,679 | 99.1 | 381 | 0.9 | 20 | 0.0 |
| 2022 | Unknown | 3 | 42.9 | 7 | 0.0 | 0 | 0.0 | 1 | 14.3 | 2 | 28.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 4 | 57.1 | 2 | 28.6 | 0 | 0.0 | 5 | 71.4 |
| 2023 | Female | 47,528 | 96.5 | 49,229 | 51.7 | 15 | 0.0 | 25,517 | 51.8 | 21,620 | 43.9 | 10 | 0.0 | 1,822 | 3.7 | 67 | 0.1 | 178 | 0.4 | 48,791 | 99.1 | 336 | 0.7 | 102 | 0.2 |
| 2023 | Male | 44,193 | 96.2 | 45,923 | 48.3 | 15 | 0.0 | 24,457 | 53.3 | 19,303 | 42.0 | 6 | 0.0 | 1,852 | 4.0 | 52 | 0.1 | 238 | 0.5 | 45,393 | 98.8 | 394 | 0.9 | 136 | 0.3 |
| 2023 | Unknown | 2 | 66.7 | 3 | 0.0 | 0 | 0.0 | 2 | 66.7 | 0 | 0.0 | 0 | 0.0 | 1 | 33.3 | 0 | 0.0 | 0 | 0.0 | 3 | 100.0 | 0 | 0.0 | 0 | 0.0 |
| 2024 | Female | 345 | 19.7 | 1,752 | 56.1 | 3 | 0.2 | 17 | 1.0 | 229 | 13.1 | 4 | 0.2 | 1,436 | 82.0 | 24 | 1.4 | 39 | 2.2 | 1,635 | 93.3 | 83 | 4.7 | 34 | 1.9 |
| 2024 | Male | 241 | 17.6 | 1,371 | 43.9 | 4 | 0.3 | 26 | 1.9 | 128 | 9.3 | 2 | 0.1 | 1,171 | 85.4 | 11 | 0.8 | 29 | 2.1 | 1,266 | 92.3 | 76 | 5.5 | 29 | 2.1 |
| 2024 | Unknown | 0 | 0.0 | 1 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 100.0 | 0 | 0.0 | 0 | 0.0 | 1 | 100.0 |

**Figure 1**

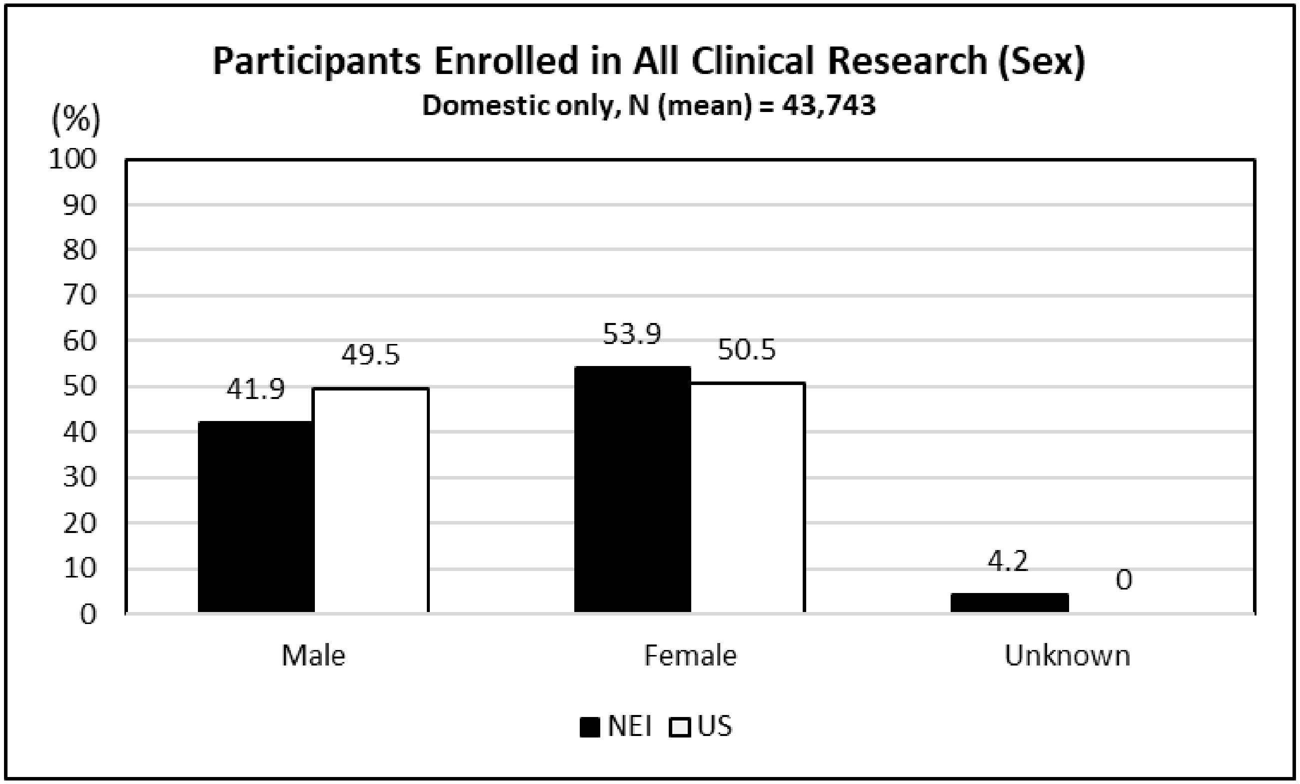

Participants Enrolled in All Clinical Research (Sex)
Domestic only, N (mean) = 43,743
(%)
100
90
80
70
60
50
40
30
20
10
0
41.9
49.5
53.9
50.5
4.2
0
Male
Female
Unknown
■ NEI ☐ US

**Figure 2**

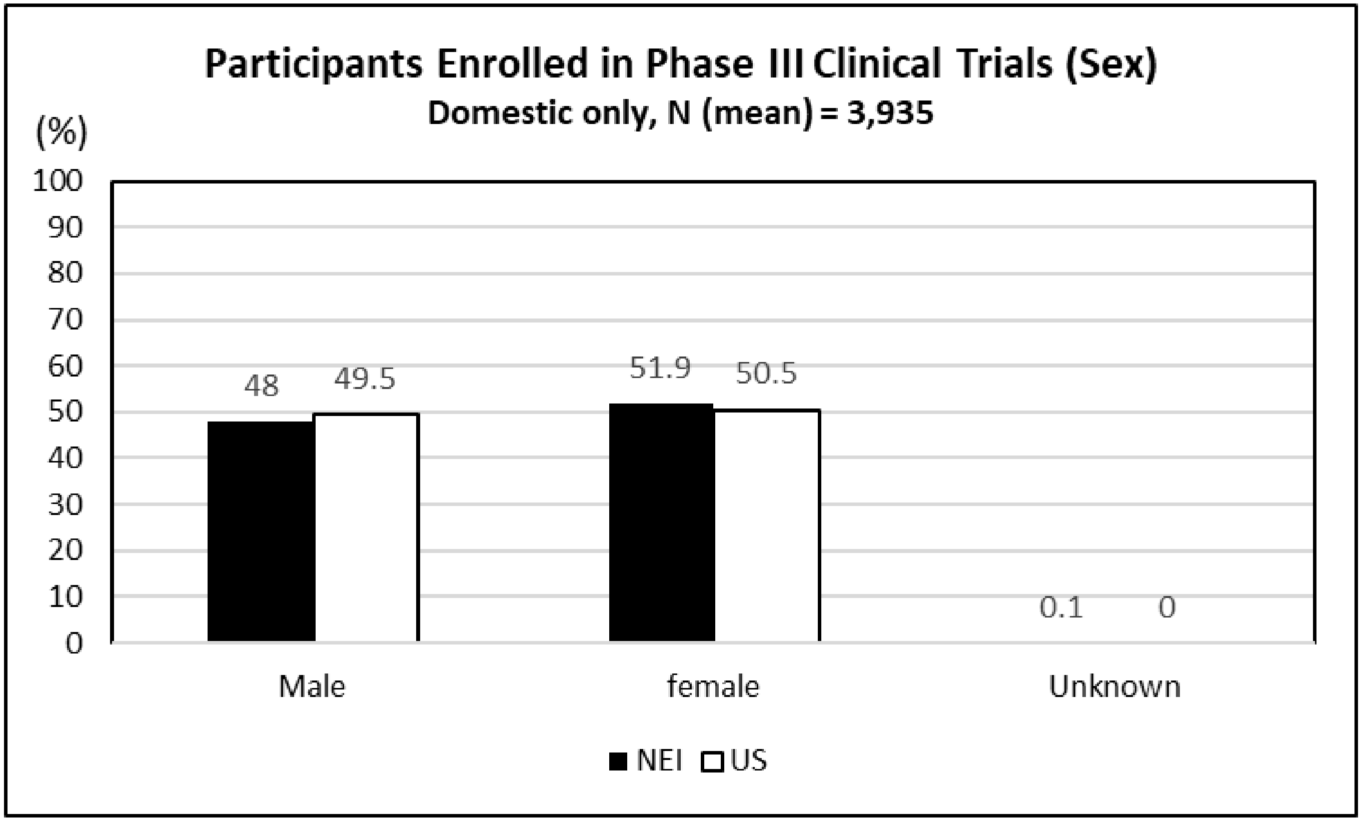

Participants Enrolled in Phase III Clinical Trials (Sex)
Domestic only, N (mean) = 3,935
(%)
100
90
80
70
60
50
40
30
20
10
0
48
49.5
51.9
50.5
0.1
0
Male
female
Unknown
■ NEI
□ US

**Figure 3**

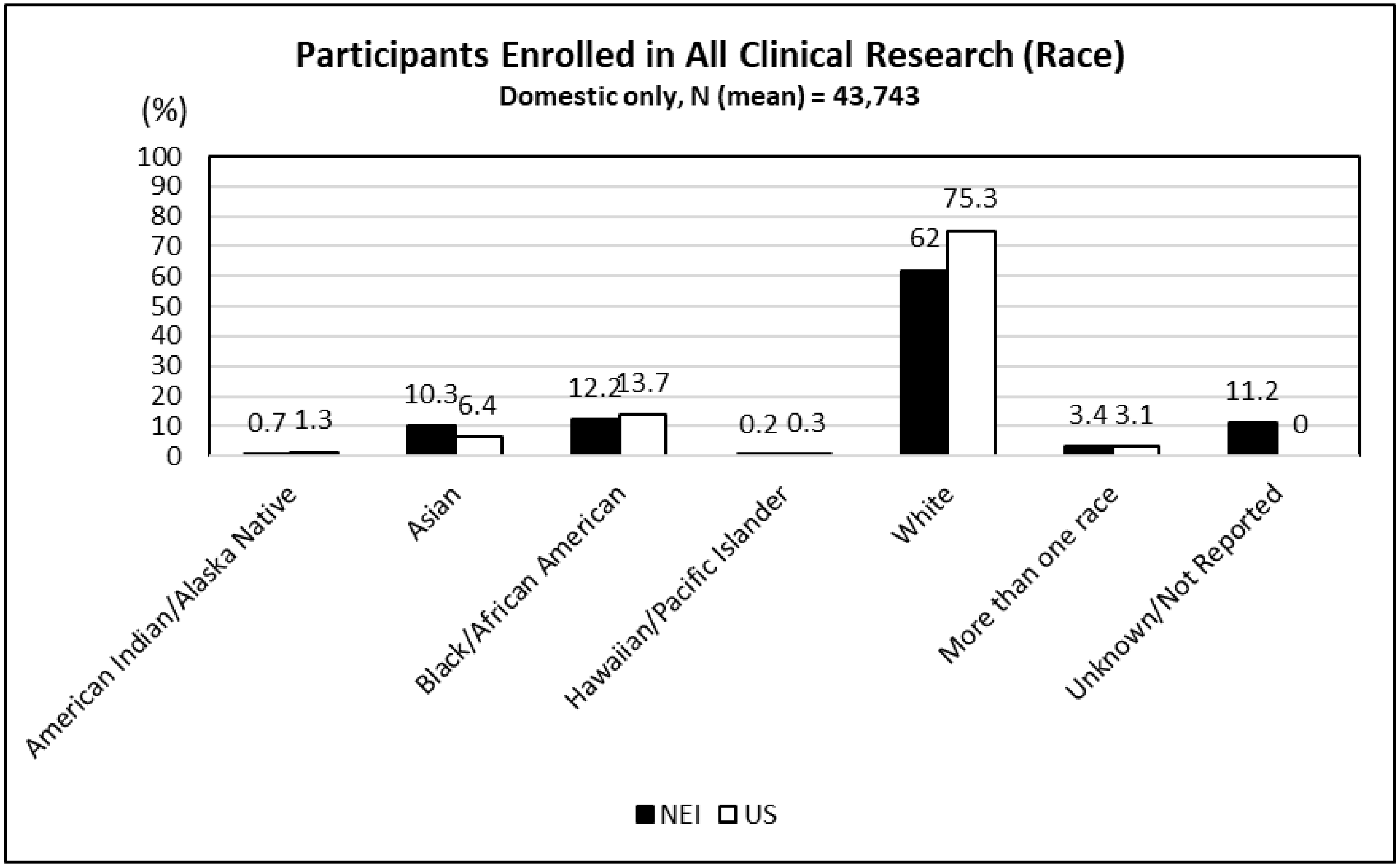
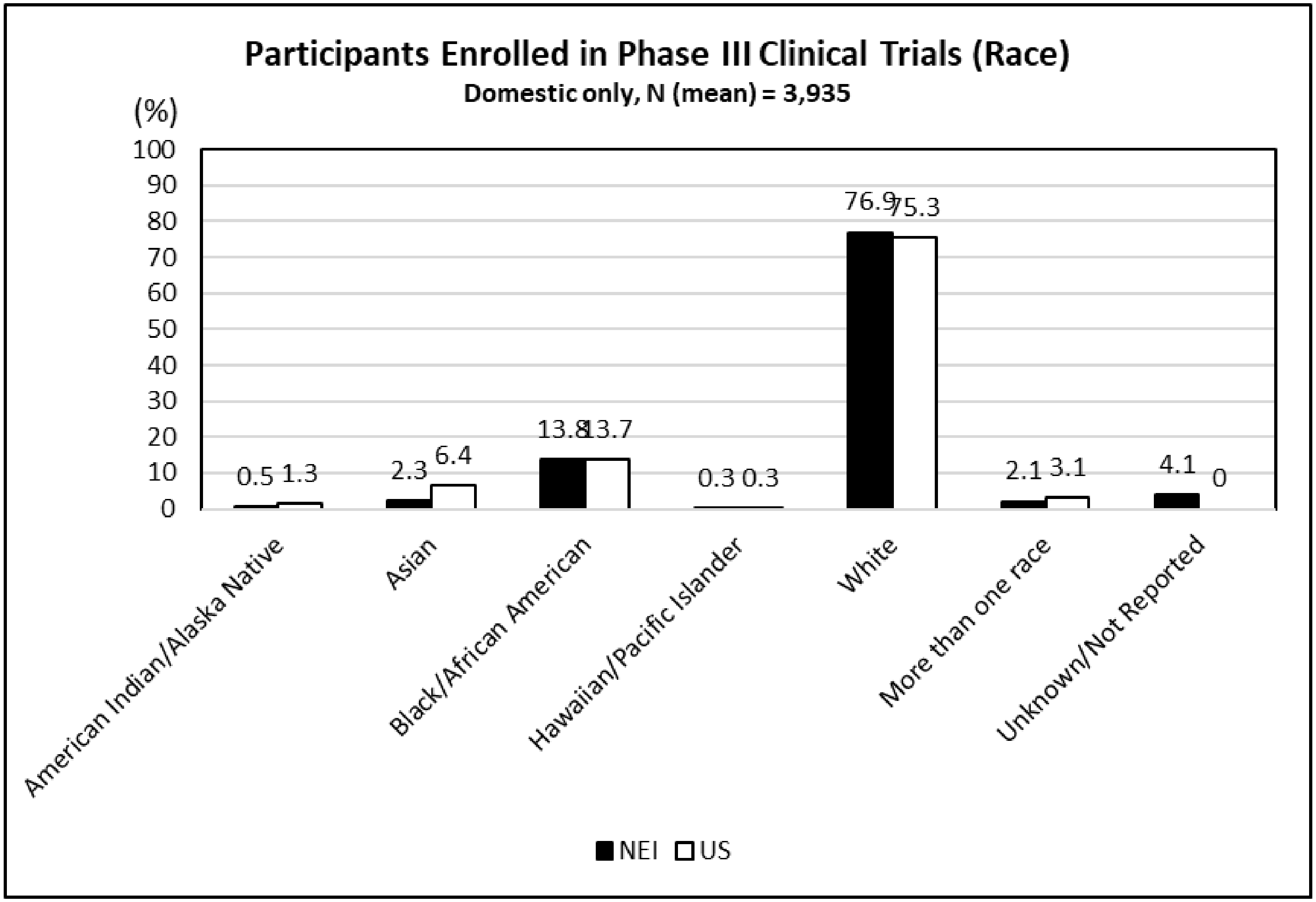

Participants Enrolled in All Clinical Research (Race)
Domestic only, N (mean) = 43,743
(%)
100
90
80
70
60
50
40
30
20
10
0
0.7
1.3
10.3
6.4
12.2
13.7
0.2
0.3
62
75.3
3.4
3.1
11.2
0
American Indian/Alaska Native
Asian
Black/African American
Hawaiian/Pacific Islander
White
More than one race
Unknown/Not Reported
■ NEI
☐ US

**Figure 4**



Participants Enrolled in Phase III Clinical Trials (Race)
Domestic only, N (mean) = 3,935
(%)
100
90
80
70
60
50
40
30
20
10
0
0.5
1.3
2.3
6.4
13.8
13.7
0.3
0.3
76.9
75.3
2.1
3.1
4.1
0
American Indian/Alaska Native
Asian
Black/African American
Hawaiian/Pacific Islander
White
More than one race
Unknown/Not Reported
■ NEI
□ US

**Figure 5**

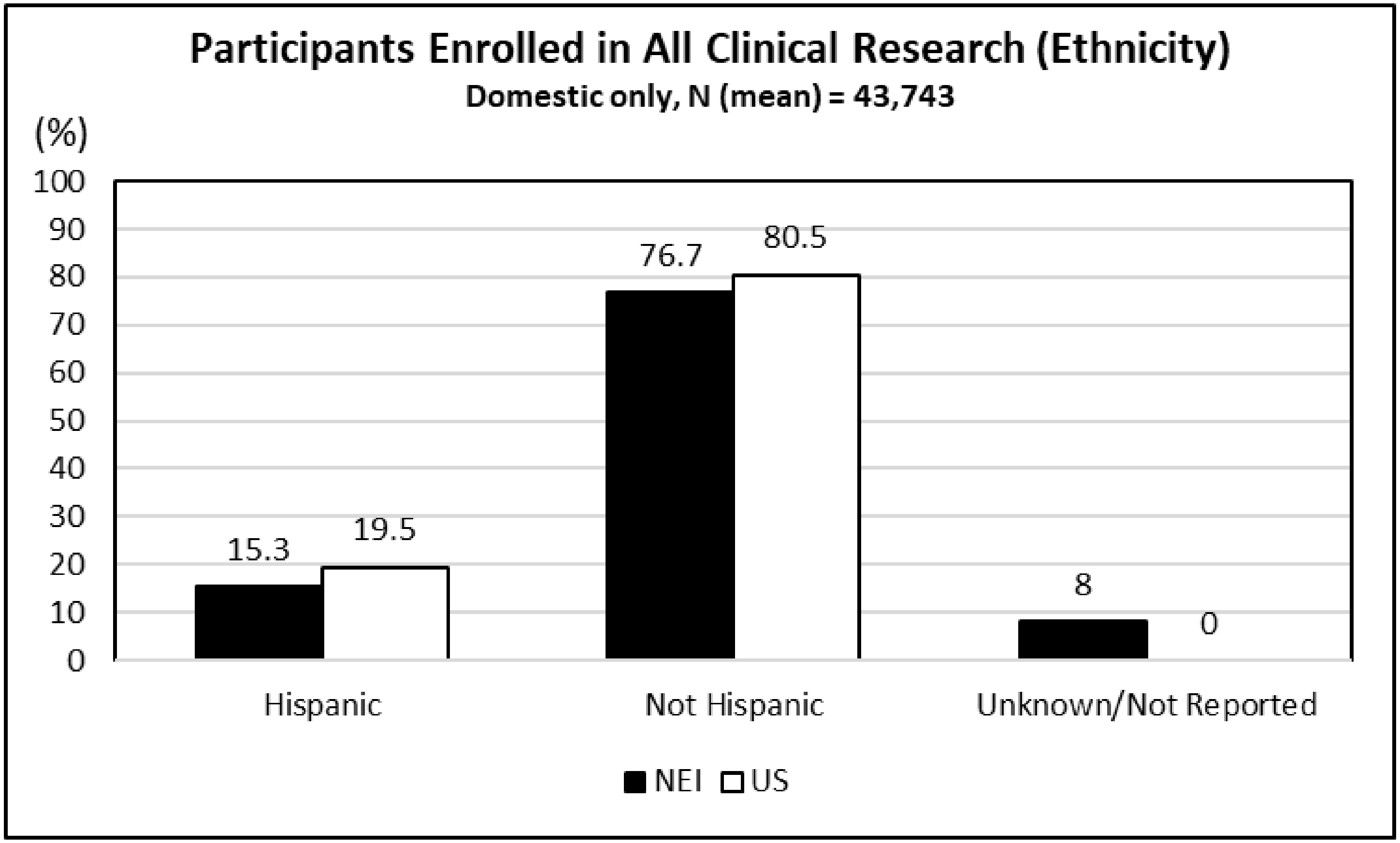

Participants Enrolled in All Clinical Research (Ethnicity)
Domestic only, N (mean) = 43,743
(%)
100
90
80
70
60
50
40
30
20
10
0
15.3
19.5
76.7
80.5
8
0
Hispanic
Not Hispanic
Unknown/Not Reported
■ NEI
☐ US

**Figure 6**

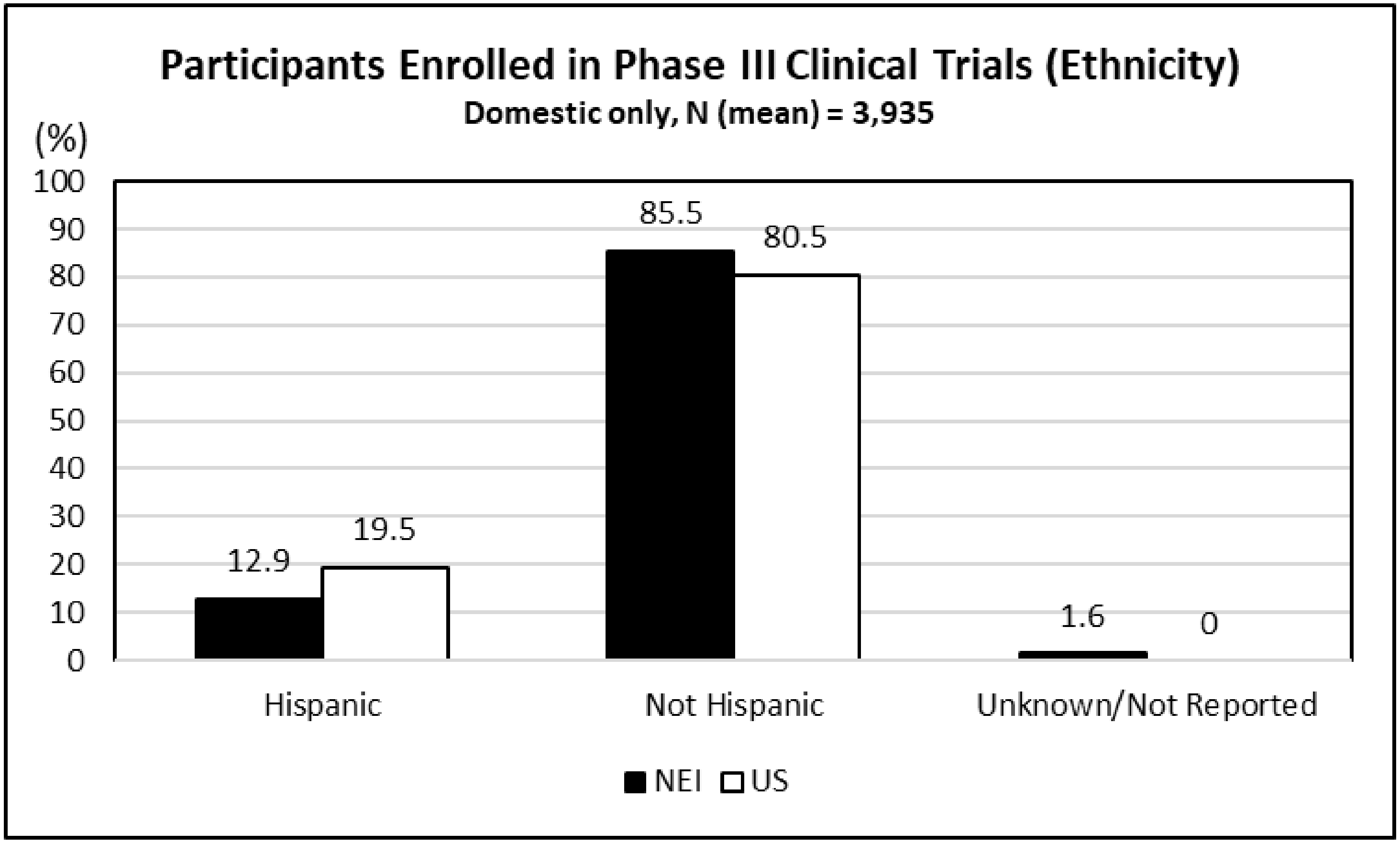
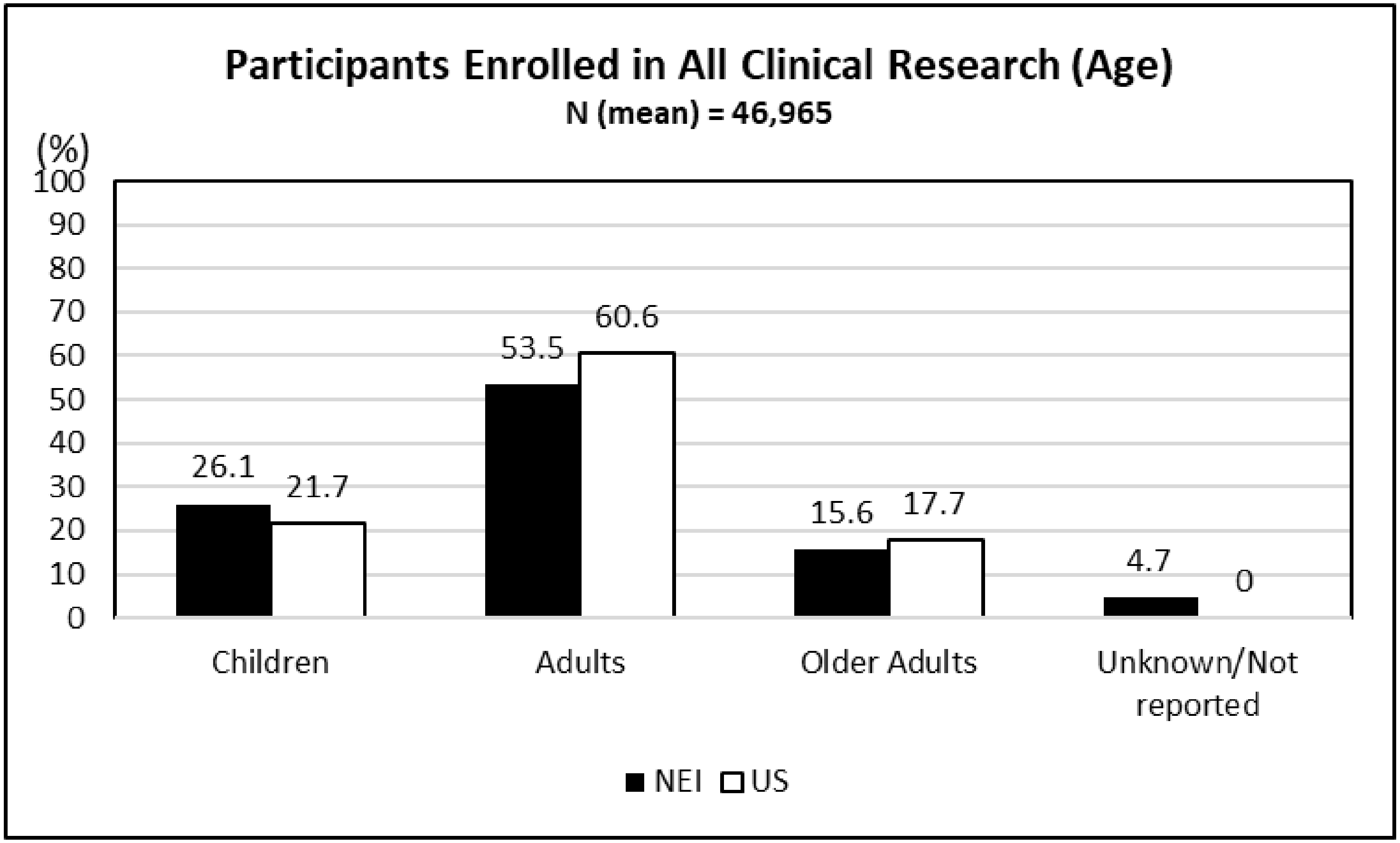

Participants Enrolled in Phase III Clinical Trials (Ethnicity)
Domestic only, N (mean) = 3,935
(%)
100
90
80
70
60
50
40
30
20
10
0
12.9
19.5
85.5
80.5
1.6
0
Hispanic
Not Hispanic
Unknown/Not Reported
■ NEI
□ US

**Figure 7**


Participants Enrolled in All Clinical Research (Age)
N (mean) = 46,965
(%)
100
90
80
70
60
50
40
30
20
10
0
26.1
21.7
53.5
60.6
15.6
17.7
4.7
0
Children
Adults
Older Adults
Unknown/Not reported
■ NEI □ US