

NCCIH Reports 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 National Center for Complementary and Integrative Health (NCCIH) is the Federal Government's lead agency for scientific research on complementary and integrative health approaches. The mission of NCCIH is to determine, through rigorous scientific investigation, the fundamental science, usefulness, and safety of complementary and integrative health approaches and their roles in improving health and health care. The field of complementary and integrative health encompasses a large and diverse array of practices, products, and disciplines. To best focus its research investment, the NCCIH Strategic Plan FY 2021-2025 (<https://www.nccih.nih.gov/about/nccih-strategic-plan-2021-2025>) outlines a framework of five major objectives:

- Objective 1: Advance Fundamental Science and Methods Development;
- Objective 2: Advance Research on the Whole Person and on the Integration of Complementary and Conventional Care;
- Objective 3: Foster Research on Health Promotion and Restoration, Resilience, Disease Prevention, and Symptom Management;
- Objective 4: Enhance the Complementary and Integrative Health Research Workforce; and
- Objective 5: Provide Objective, Evidence-Based Information on Complementary and Integrative Health Interventions.

NCCIH supports research on a diverse group of nondrug and noninvasive health practices encompassing nutritional, psychological, and physical approaches that may have originated outside of conventional medicine, many of which are gradually being integrated into mainstream health care. These include natural products, such as dietary supplements, plant-based products, and probiotics, as well as mind and body approaches, such as yoga, massage therapy, meditation, mindfulness-based stress reduction, spinal/joint manipulation, and acupuncture. In clinical practice, these approaches are often combined into multicomponent therapeutic systems, such as traditional Chinese medicine, Ayurveda, chiropractic, osteopathy, and naturopathy, that have distinctive underlying diagnostic and theoretical frameworks. Integrative health care seeks to bring conventional and complementary approaches together in a safe, coordinated way with the goal of improving clinical care for patients, restoring health, promoting resilience, and preventing disease. NCCIH has worked to advance the position that evidence-based complementary therapies should be “integrated” with and not used as an “alternative” to conventional medicine.

NCCIH's vision is that scientific evidence informs decision making by the public, health care professionals, and health policymakers regarding the integrated use of complementary health approaches in a whole person health framework. Therefore, the primary goals and objectives of the NCCIH clinical portfolio are to advance the science and practice of symptom management; develop effective, practical, personalized strategies for promoting health and well-being; and enable better evidence-based decision-making regarding complementary and integrative health approaches and their integration into health care and health promotion. In support of its research goals and objectives, the NCCIH supports an extensive portfolio of interventional clinical trials and observational studies varying in size and complexity.

Top Scientific Priorities at NCCIH (<https://www.nccih.nih.gov/about/nccih-strategic-plan-2021-2025/top-scientific-priorities>):

- Research on Whole Person Health
- Interoception Research
- Health Restoration, Resilience, Disease Prevention, and Health Promotion Across the Lifespan
- Implementation Science for Complementary and Integrative Health
- Complementary and Integrative Management of Pain
- Complex Interactions Involving Nutritional Interventions
- Enhancing the Complementary and Integrative Health Research Workforce
- Mechanisms and Biomarkers of Mind and Body Approaches
- Supporting Impactful Clinical Trials of Complementary and Integrative Health Approaches
- Communications Strategies and Tools To Enhance Scientific Literacy and Understanding of Clinical Research

II. Strategies for Ensuring Compliance

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff.

A. Peer Review

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. The National Advisory Council for Complementary and Integrative Health (NACCIH) performs

the second level of review and makes recommendations for funding to the NCCIH Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NCCIH. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

Effective January 2025, the new Simplified Framework for NIH Peer Review Criteria reorganizes peer review criteria into three central factors: importance, rigor and feasibility, and expertise and resources. Inclusion criteria and coding and plans for valid design and analysis of Phase III clinical trials, previously evaluated under Additional Review Criteria, will be integrated within Factor 2 (Rigor and Feasibility). This change will help to emphasize the importance of these criteria in evaluating scientific merit.

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. 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 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.

C. Intramural

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

D. NCCIH Training Approaches

NIH created the Inclusion Learning Path in 2024 (<https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities>) to provide a suite of on-demand trainings on inclusion policies and procedures for program staff. Staff may access the training on the NIH staff intranet. Additionally, the NIH has launched the Human Subjects System (<https://www.era.nih.gov/help-tutorials/era-training-hss.htm>) to replace the Inclusion Management System for use by grant applicants, recipients, and NIH staff.

E. **NCCIH Specific Items to Ensure Compliance with the Inclusion Policy**

Inclusion topics are discussed at the biweekly Clinical Studies Working Group (CSWG) meeting. Widely attended by NCCIH staff from the Office of Clinical and Regulatory Affairs, the Division of Extramural Research, and the Division of Extramural Activities, CSWG meetings are used to discuss specific inclusion scenarios, brainstorm approaches and adopt consensus via presentation and group discussion.

III. Analysis and Interpretation of Data

NIH-defined clinical research is medical research that involves people to test new treatments and therapies (<https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms>). NIH-defined clinical trials means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes (<https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms>). Finally, NIH-defined Phase III clinical trials are those in which the experimental drug or treatment is administered to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments (<https://www.nih.gov/health-information/nih-clinical-research-trials-you/glossary-common-terms>).

A. **FY 2022-2024 Data**

Appendix 1, Table 1 shows enrollment data tables for Fiscal Years (FY) 2016 through 2024. The last three (3) rows FY 2022-2024 report data for this triennial report, and show the total enrollment for both extramural and intramural NIH-defined clinical research, the percentage of total enrollments for females and racial and ethnic minorities, and the total enrollment in NIH-defined Phase III clinical trials.

B. **Discussion of FY 2022-FY 2024 Inclusion Data**

The appended tables (Appendix 1) show enrollment data for fiscal years (FY) 2022 through 2024.

Table 2.1 shows Total Inclusion Data Records (from Inclusion Enrollment Reports [IERs]) for NIH-Defined Extramural and Intramural Clinical Research Reported between FY 2022- FY 2024. In FY 2022, the NCCIH Extramural Program had 256 IERs for NIH-Defined Extramural and Intramural Clinical Research with 139 clinical studies in enrollment status, among which 20 involved women only. In FY 2023, the NCCIH Extramural Program had 240 IERs for NIH-Defined Extramural and Intramural Clinical Research, with 131 clinical studies in enrollment status, among which 8 involved women only. In FY 2024, the NCCIH Extramural Program had 257 IERs for NIH-Defined Extramural and Intramural Clinical Research, with 135 clinical studies in enrollment status, among which 12 involved women only. Note that “clinical studies” has been defined broadly, to

include clinical intervention trials, as well as non-interventional clinical research, epidemiologic studies, behavioral studies, and database studies.

Table 5-1-1-C shows total enrollment for all NIH-defined Clinical Research by Sex, Race and Ethnicity categories. In FY 2022, NCCIH-funded clinical research enrolled 50,427 participants, of which 25,117 (49.8 %) were women. In FY 2022, NCCIH-funded studies involved 15,006 (29.8%) minority enrollment including 361 American Indian/Alaska Native participants (0.7%), 1,892 Asian participants (3.8%), 8,265 African-American/Black participants (16.4%), 98 Native Hawaiian/Pacific Islander participants (0.2%), 816 participants reporting More than one race (1.6%), and 1,639 participants with Unknown/Not Reported Race (3.3%). Enrollment by ethnicity included 4,135 Hispanic/Latino participants (8.2%).

In FY 2023, NCCIH-funded clinical research enrolled 45,503 participants, of which 22,299 (49.0%) were women. In FY 2023, NCCIH-funded studies involved 13,780 (30.3%) minority enrollment including 352 American Indian/Alaska Native participants (0.8%), 1,245 Asian participants (2.7%), 8,395 African-American/Black participants (18.4%), 73 Native Hawaiian/Pacific Islander participants (0.2%), 661 participants reporting More than one race (1.5%), and 888 participants with Unknown/Not Reported Race (2.0%). Enrollment by ethnicity included 3,852 Hispanic/Latino participants (8.5%).

In FY 2024, NCCIH-funded clinical research enrolled 34,416 participants, of which 18,219 (52.9%) were women. In FY 2024, NCCIH-funded studies involved 10,359 (30.1%) minority enrollment including 378 American Indian/Alaska Native participants (1.1%), 823 Asian participants (2.4%), 6,867 African-American/Black participants (20.0%), 45 Native Hawaiian/Pacific Islander participants (0.1%), 470 participants reporting More than one race (1.4%), and 806 participants with Unknown/Not Reported Race (2.3%). Enrollment by ethnicity included 2,127 Hispanic/Latino participants (6.2%).

Table 2.2 shows Total Inclusion Data Records (from IERs) for NIH-Defined Extramural and Intramural Phase III Clinical Trials Reported between FY 2022- FY 2024. During this reporting period, the NCCIH Intramural Program had no IERs for NIH-Defined Phase III Clinical Trials; therefore all data presented are for the NCCIH Extramural Program. In FY 2022, the NCCIH Extramural Program had 14 total IERs for NIH-Defined Phase III Clinical Trials with 12 Phase III Clinical Trials in enrollment status, among which zero (0) involved women only. In FY 2023, the NCCIH Extramural Program had 7 total IERs for NIH-Defined Phase III Clinical Trials, with 2 Phase III Clinical Trials in enrollment status, among which zero (0) involved women only. In FY 2024, the NCCIH Extramural Program had 11 IERs for NIH-Defined Phase III Clinical Trials, with 7 Phase III Clinical Trials in enrollment status, among which zero (0) involved women only.

Table 5-2-2-C shows all enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research by sex and ethnicity. During this reporting period, the NCCIH Intramural Program had no IERs for NIH-Defined Phase III Clinical Trials; therefore all

data presented are for the NCCIH Extramural Program. In FY 2022, NCCIH-funded enrollment included 12 NIH-Defined Phase III Clinical Trials reporting enrollment with 2,856 participants enrolled, including 1,217 (42.6%) women, 1,246 (43.6%) racial minority enrollment, and 425 (14.9%) participants of Hispanic or Latino ethnicity. In FY 2023, NCCIH-funded enrollment included 2 NIH-Defined Phase III Clinical Trials reporting enrollment with 332 participants enrolled, including 148 (44.6%) women, 97 (29.2%) racial minority enrollment, and 29 (8.7%) participants of Hispanic or Latino ethnicity. In FY 2024, NCCIH-funded enrollment included 7 NIH-Defined Phase III Clinical Trials reporting enrollment with 2,162 participants enrolled, including 1,156 (53.5%) women, 540 (25.0%) racial minority enrollment, and 190 (8.8%) participants of Hispanic or Latino ethnicity. All of the NIH-defined Phase III clinical trials required valid analyses by sex and race/ethnicity.

Overall, enrollment into NCCIH-funded clinical studies has been robust, peaking in FY 2022 then declining with the conclusion of several large scale clinical trials funded in the Pain Management Collaboratory and Pragmatic Trials Collaboratory. Representation of women, and racial and ethnic minorities in NCCIH-funded NIH-defined Clinical Research and Phase III Clinical Trials have remained quite stable over the last three (3) years of the reporting period.

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 now be published annually at this website.

NCCIH Report of FY22-FY24 Inclusion Data

Appendix 1

**TABLE 1: NCCIH Summary for total NIH-Defined Extramural and Intramural Clinical Research
(FY 2016 – 2024)**

| FISCAL YEAR | ENROLLMENT | WOMEN (%) | MINORITIES (%) | HISPANIC (%) | PHASE III ENROLLMENT |
|---------------|-------------|-----------|----------------|--------------|----------------------|
| 2016 | 6,700 | 52 | 23 | 8 | 0 |
| 2017 | 9,268 | 49 | 24 | 9 | 65 |
| 2018 | 7,879 | 60 | 22 | 7 | 268 |
| 2019 | 9,343 | 58 | 25 | 6 | 268 |
| 2020 | 15,799 | 50 | 26 | 9 | 1,476 |
| 2021 | 49,100 | 52 | 27 | 6 | 1,118 |
| 2022 | 50,427 | 50 | 30 | 8 | 2,856 |
| 2023 | 45,503 | 49 | 30 | 8 | 332 |
| 2024 | 34,416 | 53 | 30 | 6 | 2,162 |
| US Population | 2020 Census | 51 | 40 | 18 | - |

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2021 and 2023

| 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 | 256 | 117 | 139 | 139 | 0 | 20 | 1 | 118 |
| 2023 | 240 | 109 | 131 | 131 | 0 | 8 | 3 | 120 |
| 2024 | 257 | 122 | 135 | 134 | 1 | 12 | 2 | 121 |

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

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 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 | 14 | 2 | 12 | 12 | 0 | 0 | 0 | 12 |
| 2023 | 7 | 5 | 2 | 2 | 0 | 0 | 0 | 2 |
| 2024 | 11 | 4 | 7 | 7 | 0 | 0 | 0 | 7 |

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

Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex, 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 | 7,964 | 31.7 | 25,117 | 49.8 | 193 | 0.8 | 893 | 3.6 | 4,791 | 19.1 | 44 | 0.2 | 18,198 | 72.5 | 404 | 1.6 | 594 | 2.4 | 22,988 | 91.5 | 1,873 | 7.5 | 256 | 1.0 |
| 2022 | Male | 6,956 | 28.1 | 24,727 | 49.0 | 167 | 0.7 | 994 | 4.0 | 3,469 | 14.0 | 54 | 0.2 | 19,100 | 77.2 | 401 | 1.6 | 542 | 2.2 | 22,304 | 90.2 | 2,195 | 8.9 | 228 | 0.9 |
| 2022 | Unknown | 86 | 14.8 | 583 | 1.2 | 1 | 0.2 | 5 | 0.9 | 5 | 0.9 | 0 | 0.0 | 58 | 9.9 | 11 | 1.9 | 503 | 86.3 | 89 | 15.3 | 67 | 11.5 | 427 | 73.2 |
| 2023 | Female | 7,198 | 32.3 | 22,299 | 49.0 | 178 | 0.8 | 578 | 2.6 | 4,753 | 21.3 | 25 | 0.1 | 16,099 | 72.2 | 326 | 1.5 | 340 | 1.5 | 19,183 | 86.0 | 1,633 | 7.3 | 1,483 | 6.7 |
| 2023 | Male | 6,522 | 28.6 | 22,795 | 50.1 | 170 | 0.7 | 661 | 2.9 | 3,634 | 15.9 | 46 | 0.2 | 17,644 | 77.4 | 307 | 1.3 | 333 | 1.5 | 19,597 | 86.0 | 2,202 | 9.7 | 996 | 4.4 |
| 2023 | Unknown | 60 | 14.7 | 409 | 0.9 | 4 | 1.0 | 6 | 1.5 | 8 | 2.0 | 2 | 0.5 | 146 | 35.7 | 28 | 6.8 | 215 | 52.6 | 100 | 24.4 | 17 | 4.2 | 292 | 71.4 |
| 2024 | Female | 6,076 | 33.3 | 18,219 | 52.9 | 201 | 1.1 | 414 | 2.3 | 4,312 | 23.7 | 22 | 0.1 | 12,634 | 69.3 | 291 | 1.6 | 345 | 1.9 | 15,761 | 86.5 | 1,044 | 5.7 | 1,414 | 7.8 |
| 2024 | Male | 4,262 | 26.7 | 15,985 | 46.4 | 177 | 1.1 | 408 | 2.6 | 2,553 | 16.0 | 23 | 0.1 | 12,349 | 77.3 | 169 | 1.1 | 306 | 1.9 | 13,960 | 87.3 | 1,073 | 6.7 | 952 | 6.0 |
| 2024 | Unknown | 21 | 9.9 | 212 | 0.6 | 0 | 0.0 | 1 | 0.5 | 2 | 0.9 | 0 | 0.0 | 44 | 20.8 | 10 | 4.7 | 155 | 73.1 | 46 | 21.7 | 10 | 4.7 | 156 | 73.6 |

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 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex, 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 | 487 | 40.0 | 1,217 | 42.6 | 14 | 1.2 | 40 | 3.3 | 269 | 22.1 | 9 | 0.7 | 788 | 64.7 | 24 | 2.0 | 73 | 6.0 | 1,034 | 85.0 | 159 | 13.1 | 24 | 2.0 |
| 2022 | Male | 759 | 46.7 | 1,625 | 56.9 | 13 | 0.8 | 63 | 3.9 | 396 | 24.4 | 14 | 0.9 | 1,000 | 61.5 | 36 | 2.2 | 103 | 6.3 | 1,318 | 81.1 | 266 | 16.4 | 41 | 2.5 |
| 2022 | Unknown | 0 | 0.0 | 14 | 0.5 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 2 | 14.3 | 0 | 0.0 | 12 | 85.7 | 2 | 14.3 | 0 | 0.0 | 12 | 85.7 |
| 2023 | Female | 42 | 28.4 | 148 | 44.6 | 0 | 0.0 | 4 | 2.7 | 28 | 18.9 | 0 | 0.0 | 113 | 76.4 | 0 | 0.0 | 3 | 2.0 | 134 | 90.5 | 11 | 7.4 | 3 | 2.0 |
| 2023 | Male | 54 | 29.7 | 182 | 54.8 | 2 | 1.1 | 1 | 0.5 | 35 | 19.2 | 0 | 0.0 | 139 | 76.4 | 1 | 0.5 | 4 | 2.2 | 164 | 90.1 | 17 | 9.3 | 1 | 0.5 |
| 2023 | Unknown | 1 | 50.0 | 2 | 0.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 2 | 100.0 | 0 | 0.0 | 0 | 0.0 | 1 | 50.0 | 1 | 50.0 | 0 | 0.0 |
| 2024 | Female | 274 | 23.7 | 1,156 | 53.5 | 9 | 0.8 | 14 | 1.2 | 132 | 11.4 | 0 | 0.0 | 900 | 77.9 | 45 | 3.9 | 56 | 4.8 | 1,032 | 89.3 | 98 | 8.5 | 26 | 2.2 |
| 2024 | Male | 263 | 27.0 | 974 | 45.1 | 10 | 1.0 | 29 | 3.0 | 122 | 12.5 | 0 | 0.0 | 732 | 75.2 | 26 | 2.7 | 55 | 5.6 | 863 | 88.6 | 90 | 9.2 | 21 | 2.2 |
| 2024 | Unknown | 3 | 9.4 | 32 | 1.5 | 0 | 0.0 | 0 | 0.0 | 1 | 3.1 | 0 | 0.0 | 16 | 50.0 | 0 | 0.0 | 15 | 46.9 | 14 | 43.8 | 2 | 6.3 | 16 | 50.0 |