



National Center for  
Complementary and  
Integrative Health

## NCCIH Report of FY16-18 Inclusion Data

### I. Background/Overview

- A. The mission of NCCIH is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care. Research of interventions supported by the NCCIH clinical portfolio is comprised primarily of natural product-based and mind/body-based interventions. Generation of an evidence base for such interventions is crucial for informing decision-making by the public, by health care professionals, and by health policymakers regarding the use and integration of complementary and integrative health approaches. The primary goals and objectives of the NCCIH clinical portfolio are therefore 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.
- B. 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. As NCCIH-supported work is focusing on generating a knowledge base for many natural product and mind/body interventions, the portfolio includes primarily early-phase clinical research in these areas. Clinical research efforts are therefore focused on formal intervention development, pilot and feasibility testing, as well as some associated mechanistic studies. In view of the goals and objectives of the NCCIH research program, larger multi-center clinical trials of these interventions are not a current focus, although the progress in developing a deeper evidence base will ultimately inform plans for larger trials of interventions that demonstrate promise in early-phase testing. In view of the focus on early-phase testing and intervention development, maximizing enrollment diversity may not be feasible or warranted in such early small studies. Progression from early-phase to larger trials of efficacy or effectiveness, however, would incorporate the need for maximizing enrollment diversity to address concerns of generalizability of research results.

Data from the National Health Interview Survey (NHIS) over the last decade has reported extensive public use of many complementary practices and approaches that are studied within the NCCIH portfolio (see NHIS publications list in section IV). There is extensive use primarily

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by educated White women in the US. Consistent with these reports, the enrolled cohort in the general NCCIH-funded program has revealed a preponderance of White women in the US.

### II. Strategies for Ensuring Compliance

#### A. Peer Review Process

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/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race, and ethnicity. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex/gender, 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.

#### 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 the requirement for sex/gender 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 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, gender, 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

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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.

### **III. NCCIH Training Approaches**

Institute Program Officials/Program Directors and Scientific Review Officers attended the May 11, 2018 training, Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts. Staff may access the archived training on the NIH staff intranet.

### **IV. Analysis and Interpretation of Inclusion Data**

#### **A. FY16-18 Data**

See attached tables in Appendix 1.

#### **B. Discussion of FY16-FY18 Inclusion Data**

The appended tables (Appendix 1) show enrollment data for fiscal years (FY) 2016 through 2018.

Table 2.1 shows Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported between FY 2016- FY 2018. In FY 16, the NCCIH Extramural Program had 75 Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research with 66 clinical studies in enrollment status, among which 8 involved women only. In FY 2017, the NCCIH Extramural Program had 104 Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research, with 87 clinical studies in enrollment status, among which 9 involved women only. In FY 2018, the NCCIH Extramural Program had 102 Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research, with 80 clinical studies in enrollment status, among which 10 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/ Gender, Race and Ethnicity categories. In FY 2016, NCCIH-funded clinical research enrolled 6,700 participants, 51.7% female and 48.2% male. In FY 16, NCCIH-funded studies involving 23% minority enrollment including 540 African-American/ Black participants (16%), 217 Asian participants (6.5%), 85 American Indian/ Alaska Native participants (2.5%), 27 Native Hawaiian/

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Pacific Islander participants (0.8%), 203 participants reporting More than one race (6%) and 542 Hispanic/ Latino participants (16%). The figures provided are adjusted for participants that are both Hispanic and of another racial minority category.

In FY 2017, NCCIH-funded clinical research enrolled 9,268 participants, 49% female and 50.3% male. In FY 17, NCCIH-funded studies involving 24% minority enrollment including 862 African-American/ Black participants (18.8%), 331 Asian participants (7.2%), 65 American Indian/ Alaska Native participants (1.4%), 29 Native Hawaiian/ Pacific Islander participants (0.7%), 278 participants reporting More than one race (6%) and 816 Hispanic/ Latino participants (17.8%).

In FY 2018, NCCIH-funded clinical research enrolled 7,879 participants, 59.6% female and 40.3% male. In FY 18, NCCIH-funded studies involving 22% minority enrollment including 662 African-American/ Black participants (18.8%), 416 Asian participants (10.4%), 39 American Indian/ Alaska Native participants (1%), 26 Native Hawaiian/ Pacific Islander participants (0.7%), 231 participants reporting More than one race (5.8%) and 554 Hispanic/ Latino participants (14%).

Table 5-3-2-C shows all enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research by sex/ gender and ethnicity. In FY 16, no NCCIH-funded enrollment involved Phase III clinical research. In FY 17, NCCIH-funded enrollment included 1 Phase III clinical trial with 65 participants enrolled including 23% female enrollment, 76.9% male enrollment and 31% minority enrollment. In FY 18, NCCIH-funded enrollment included 1 Phase III clinical trial with 268 participants enrolled including 25.7% female enrollment, 74.3% male enrollment and 41% minority enrollment. The Phase III study funded in FY2018 requires valid analysis.

The RCDC Website <https://report.nih.gov/RISR/> displays the typical representation of participants in human subject studies enrolled in FY2018 projects associated with the listed research, condition, or disease category. Median percent participation is presented for each demographic variable.

## V. Additional information

## **NCCIH Report of FY16-18 Inclusion Data**

The 21<sup>st</sup> 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/gender 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 21<sup>st</sup> 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 first triennial report provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018. Section IV of the [Report of the Advisory Committee on Research on Women's Health](#) includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2015 and 2016.

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## **Appendix 1**

## Section 2: 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 FY2016 and FY2018**

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*
2016	75	9	66	66	0	8	0	58
2017	104	17	87	86	1	9	0	78
2018	102	22	80	78	2	10	0	70

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

## 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 FY2016 and FY2018**

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*
2016	0	0	0	0	0	0	0	0
2017	2	1	1	1	0	0	0	1
2018	2	0	2	1	1	0	0	2

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

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/Gender by Race and Ethnicity

Year	Sex Gender	Total Enrollment		% Enrollment by Race and Ethnicity																Unknown Not Reported		Unknown Not Reported			
		Minority	% Minority	Indian Alaska Native	American Indian Alaska Native	Asian	% Asian	Black American	% Black American	Hawaiian Pacific Islander	% 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		
2016	Female	927	26.8	3,461	51.7	29	0.8	127	3.7	344	9.9	15	0.4	2,545	73.5	119	3.4	282	8.1	2,890	83.5	351	10.1	220	6.4
2016	Male	608	18.8	3,232	48.2	56	1.7	90	2.8	196	6.1	12	0.4	2,604	80.6	84	2.6	190	5.9	2,910	90.0	191	5.9	131	4.1
2016	Unknown	2	28.6	7	0.1	0	0.0	0	0.0	1	14.3	0	0.0	5	71.4	0	0.0	1	14.3	4	57.1	1	14.3	2	28.6
2017	Female	1,310	28.8	4,543	49.0	37	0.8	185	4.1	535	11.8	12	0.3	3,405	75.0	147	3.2	222	4.9	3,913	86.1	475	10.5	155	3.4
2017	Male	941	20.2	4,668	50.3	28	0.6	146	3.1	327	7.0	17	0.4	3,814	81.7	131	2.8	205	4.4	4,204	90.1	341	7.3	123	2.6
2017	Unknown	3	4.4	68	0.7	0	0.0	0	0.0	0	0.0	1	1.5	15	22.1	0	0.0	52	76.5	12	17.6	2	2.9	54	79.4
2018	Female	1,094	22.9	4,767	59.6	23	0.5	244	5.1	433	9.1	12	0.3	3,761	78.9	139	2.9	155	3.3	4,362	91.5	311	6.5	94	2.0
2018	Male	712	22.1	3,222	40.3	16	0.5	172	5.3	229	7.1	14	0.4	2,563	79.5	92	2.9	136	4.2	2,884	89.5	243	7.5	95	2.9
2018	Unknown	2	22.2	9	0.1	0	0.0	0	0.0	1	11.1	0	0.0	6	66.7	1	11.1	1	11.1	8	88.9	0	0.0	1	11.1

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

**US Site Enrollment: All NIH-Defined Clinical Research**

Table 5-3-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority		% American Indian Alaska Native												% More Than One Race		% Unknown Not Reported		% Not Hispanic		% Not Hispanic Latino		% Unknown Not Reported	
		Minority	% Minority	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		
2016	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2016	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2017	Female	6	40.0	0	0.0	0	0.0	1	6.7	0	0.0	13	86.7	1	6.7	0	0.0	11	73.3	4	26.7	0	0.0		
2017	Male	14	28.0	1	2.0	0	0.0	2	4.0	0	0.0	46	92.0	1	2.0	0	0.0	40	80.0	10	20.0	0	0.0		
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2018	Female	31	46.3	1	1.5	0	0.0	11	16.4	3	4.5	49	73.1	3	4.5	0	0.0	49	73.1	17	25.4	1	1.5		
2018	Male	80	40.8	1	0.5	4	2.0	15	7.7	4	2.0	164	83.7	8	4.1	0	0.0	137	69.9	59	30.1	0	0.0		
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

Table 5-3-3-C. US Site Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority		% American Indian Alaska Native												% More Than One Race		% Unknown Not Reported		% Not Hispanic		% Not Hispanic Latino		% Unknown Not Reported	
		Minority	% Minority	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		
2016	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2016	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2017	Female	6	40.0	0	0.0	0	0.0	1	6.7	0	0.0	13	86.7	1	6.7	0	0.0	11	73.3	4	26.7	0	0.0		
2017	Male	14	28.0	1	2.0	0	0.0	2	4.0	0	0.0	46	92.0	1	2.0	0	0.0	40	80.0	10	20.0	0	0.0		
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2018	Female	31	46.3	1	1.5	0	0.0	11	16.4	3	4.5	49	73.1	3	4.5	0	0.0	49	73.1	17	25.4	1	1.5		
2018	Male	80	40.8	1	0.5	4	2.0	15	7.7	4	2.0	164	83.7	8	4.1	0	0.0	137	69.9	59	30.1	0	0.0		
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

Table 5-3-4-C. US Site Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority		% American Indian Alaska Native												% More Than One Race		% Unknown Not Reported		% Not Hispanic		% Not Hispanic Latino		% Unknown Not Reported	
		Minority	% Minority	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		
2016	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2016	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2017	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2017	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2018	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2018	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

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