

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

2016-2018 TRIENNIAL ADVISORY COUNCIL REPORT

CERTIFYING COMPLIANCE WITH THE

NIH POLICY ON INCLUSION GUIDELINES

A handwritten signature in black ink, appearing to read "NES", with a long horizontal flourish extending to the right.

Norman E. Sharpless, M.D.

Director

National Cancer Institute

February 2019

National Cancer Institute
Triennial Report

Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2016 – FY2018

I. BACKGROUND/OVERVIEW

As required by the NIH Revitalization Act of 1993 (PL 103-43), the advisory board or council of each Institute must prepare a biennial report describing the manner in which the Institute has complied with the NIH guidelines on inclusion of women and minorities as subjects in clinical research studies and the NIH requirements for tracking and reporting enrollment to clinical research studies by ethnicity, race and sex/gender. The 21st Century Cures Act amended the frequency of the report from biennial to triennial. Thus, this first triennial report provides information on inclusion of participants in NIH clinical research from FY 2016–2018.

A. Mission Statement

The National Cancer Institute (NCI) is part of the National Institutes of Health (NIH), which is one of 11 agencies that comprise the Department of Health and Human Services (HHS). NCI, established under the National Cancer Institute Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of NCI and created the National Cancer Program. Over the years, legislative amendments have maintained NCI authorities and responsibilities and added new information dissemination mandates as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice. NCI coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients. Specifically, the Institute:

- Provides research grants and cooperative agreements to coordinate and support research projects conducted by universities, hospitals, research foundations, and businesses throughout this country and abroad. Conducts research in its own laboratories and clinics.
- Supports education and training in fundamental sciences and clinical disciplines for participation in basic and clinical research programs and treatment programs relating to cancer through career awards, training grants, and fellowships.
- Supports research projects in cancer control.

- Supports a national network of cancer centers.
- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.
- Encourages and coordinates cancer research by industrial concerns where such concerns evidence a particular capability for programmatic research.
- Collects and disseminates information on cancer detection, diagnosis, treatment, prevention, control, palliative care, and survivorship
- Supports construction of laboratories, clinics, and related facilities necessary for cancer research.

B. NCI's Inclusion Portfolio

The inclusion data includes epidemiological, population-based interventions and therapeutic trials according to the NIH definition of clinical research and supported by the following NCI Divisions and Centers:

Extramural Research

Division of Cancer Biology

Division of Cancer Control and Population Sciences

Division of Cancer Prevention

Division of Cancer Treatment and Diagnosis

OD, Center for Cancer Training

OD, Center for Cancer Genomics

OD, Center for Global Health

OD, Center for Strategic Scientific Initiatives

OD, Center to Reduce Cancer Health Disparities

OD, Office of Cancer Centers

OD, Office of HIV and AIDS Malignancy

OD, Small Business Innovation Research Development Center

Intramural Research

Division of Cancer Epidemiology and Genetics

Center for Cancer Research

II. STRATEGIES FOR ENSURING COMPLIANCE

The policies and procedures employed by NCI staff to collect, implement, and disseminate information on compliance were reviewed with the Board. Data was presented to the NCAB indicating the overall aggregate accrual to all clinical research as defined by the NIH Office of Extramural Research, as well as subsets of specific types of trials, such as observational vs therapeutic treatment trials.

It was emphasized that it is the responsibility of the staff within individual NCI program divisions, offices, and centers to work with grantees to assure that the original accrual projections are actually attained as the study progresses, and that data indicating significant differences based on gender, race and/or ethnicities must be noted in analyses and reports of study outcomes.

The implementation of inclusion guidelines involves the participation of review, extramural and intramural program, monitoring, policy, and grants management staff. The responsibilities of each are as follow:

A. Peer Review

Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion based on 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.

B. Program Monitoring and Grants Management Oversight

Prior to an award, Program Officials/Program Directors are responsible for assuring that the inclusion information plans are scientifically appropriate. If issues are raised in review, program staff notifies the Principal Investigator(s), who must address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding. NCI staff work with applicants to ensure appropriate revisions are made. An award is not issued until an acceptable resolution is received and the bar has been removed. Program staff monitors annual progress reports to ascertain overall enrollment and consults with the principal investigator, when needed. 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 enrollment 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 of the proposed clinical research study. 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 investigator and reviewed by the pertinent Institutional Review Board (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. NCI Training Approaches

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

E. Additional NCI-specific Items Used to Ensure Compliance with the Inclusion Policy

The central branch for assuring the data entry and quality of extramural reports is in the NCI Division of Extramural Activities (DEA). As Director of the DEA, Dr. Paulette Gray oversees the process and provides leadership to all NCI divisions, offices, and centers. Ms. Beth Buschling serves as Lead NCI Representative to the NIH Inclusion Operating Procedures Workgroup. Ms. Buschling and Ms. Clarissa Douglas of the Research Analysis Evaluation Branch, DEA, organize and coordinate the NCI Accrual Working Group with members from the extramural DOCs (see Appendix E). Meetings are held monthly (or as needed) from September to December to resolve reporting issues, reconcile data discrepancies, coordinate training, and communicate policy issues between the NCI Accrual Working Group and the NIH Inclusion Operating Procedures Workgroup.

III. ANALYSIS AND INTERPRETATION OF DATA

NCI Clinical Research: Fiscal Years (FY) 2016-2018

The appended tables show detailed information on the total number of studies/protocols that are referred to as inclusion data records (IDRs) in the NIH Human Subjects System and detailed enrollment data for FY 2016-2018. NCI's inclusion data is as follows:

In FY 2016, there were 2,666 extramural and intramural clinical research IDRs, including Phase III and other clinical studies, of which 2,372 IDRs reported human subject participation. Of these, 2,114 (89.1%) were domestic protocols and 258 (10.9%) were foreign protocols. In FY 2017, there were 2,733 extramural and intramural clinical research IDRs, including Phase III and

other clinical studies, of which 2,402 IDRs reported human subject participation. Of these, 2,145 (89.3%) were domestic protocols and 257 (10.7%) were foreign protocols. In FY 2018, 3,329 extramural and intramural clinical research IDRs were reported, including Phase III and other clinical studies. Of the 3,329 IDRs, 2,864 reported human subject participation of which 2,483 (86.7%) were domestic protocols and 381 (13.3%) were foreign protocols. As indicated by the data, there was an increase in the number of IDRs reporting human subject participation in FY 2016-2018 (see Table 2-1, Appendix A).

In FY 2016, the total number of human subject participants was 10,376,738, which included 5,630,488 (54.3%) females, 4,707,527 (45.4%) males, and 38,723 (0.4%) unknown or not reported sex/gender. In FY 2017, the total number of participants was 8,450,627 (3,759,860 (44.5% females; 4,586,463 (54.3%) males, and 104,304 (1.2%) unknown or not reported sex/gender). The decrease in FY 2016 resulted from the end of an intramural study (General Studies in of Epidemiology) and two extramural studies (Evaluating Prior Cancer Exclusion Policy to increase Lung Cancer Trial Accrual as well as a Long-Term Multidisciplinary Study of Cancer in Women: The Nurses' Health Study). From FY 2017-2018, decreases in both female and male participants were the result of a large epidemiology international study (Spatio-Temporal Epidemiology: Methods and Applications) that ended in FY 2017. The study included 4,736,495 participants. In FY 2018, the total number of participants were 3,287,847 (1,921,595 (58.4%) females; 1,168,054 (35.5%) males; and, 198,198 (6.0%) unknown or not reported sex/gender (see Table 5-1-1-C, Appendix B).

Table 5-1-2-C, in Appendix C, show only U.S. studies. This data reflects more accurately the percentages across the race and ethnic categories for FY 2016-2018. The largest minority group was Black or African American at 4.1% females and 7.2% males in FY 2016; 6.8% females and 7.6% males in FY 2017; and, 9.7% females and 6.1% males in FY 2018. The smallest minority group was Native Hawaiian/Pacific Islander at 0.1% females and 0.2% males in FY 2016; 0.2% females and 0.2% males in FY 2017; and 0.2% females and 0.1% males in FY 2018.

Phase III Clinical Trials

In FY 2016, there were 225 Phase III studies/protocols or IDRs as referred to in the NIH Human Subjects System (HSS), of which 206 IDRs reported human subject participation. Of these, 137 (66.5%) were domestic protocols and 69 (33.5%) were foreign protocols. In FY 2017, there were 242 Phase III studies/protocols or IDRs, of which 223 IDRs reported human subject participation. Of these, 148 (66.4%) were domestic protocols and 75 (33.6%) were foreign protocols. In FY 2018, there were 325 Phase III studies/protocols or IDRs, of which 295 IDRs reported human subject participation. Of these, 197 (66.8%) were domestic protocols and 98 (33.2%) were foreign protocols. This shows a steady increase in the numbers of IDRs reporting human subject participation in FY 2016 through FY 2018 (see Table 2-2, Appendix D).

In FY 2016, the total number of participants enrolled in Phase III studies were 94,193; 57,150 (60.7%) of the participants were females, 36,974 (39.3%) were males, and 69 (0.1%) were unknown or not reported sex/gender. In the ethnicity category, 76,769 (81.5%) of the participants were not Hispanic, 15,025 (16.0%) were Hispanic, and 2,399 (2.5%) were unknown

or not reported ethnicity. In FY 2017, the total number of participants were 109,824; 64,678 (58.9 %) of the participants were females, 45,076 (41.0%) were males, and 70 (0.1%) were unknown or not reported sex/gender. In the ethnicity category, 89,480 (81.5%) of the participants were not Hispanic, 16,838 (15.3%) were Hispanic, and 3,506 (3.2%) were unknown or not reported ethnicity. In FY 2018, the total number of participants were 146,000; 91,264 (62.5%) of the participants were females, 54,662 (37.4%) were males, and 74 (0.1%) were unknown or not reported sex/gender. In the ethnicity category, 119,332 (81.7%) of the participants were not Hispanic, 20,375 (14.0%) were Hispanic; and, 6,293 (4.3%) were unknown or not reported ethnicity (see Table 5-2-2-C, Appendix E).

In FY 2016, the largest minority groups were Asian (10.3 % males and 6.9% females), and Black or African American (9.4% females and 8.7% males). In FY 2017, the largest minority groups were Black or African American (9.7% females and 9.7% males), and Asian (7.0% males and 6.7% females). In FY 2018, the largest minority groups were Black or African American (8.0% females and 10.1% males), and More than One Race (9.9% females and 6.3% males). In FY 2016, the smallest minority group was Native Hawaiian/Pacific Islanders (0.1% females and 0.1% males). In FY 2017, the smallest minority groups were Native Hawaiian/Pacific Islanders (0.2% females and 0.2% males), and More than One Race (0.2% females and 0.2% males). In FY 2018, the smallest minority group was Native Hawaiian/Pacific Islander (0.3% females and 0.2% males) (see Table 5-2-2-C, Appendix E).

IV. NIH RESEARCH, CONDITION, AND DISEASE CATEGORIZATION (RCDC) INCLUSION REPORT

The FY 2018 inclusion data by Research, Condition, and Disease Categorization (RCDC) category will be available in January 2019, accessible at <https://report.nih.gov/RISR/>.

V. ADDITIONAL INFORMATION

A. Policy changes related to the 21st Century Cures Act.

The 21st Century Cures Act, enacted 13 December 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 28 November 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 <https://clinicaltrials.gov/>. This requirement is effective for competing grant awards on or after 13 December 2017, as well as contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children Policy on 19 December 2017. The revised policy (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 25 January 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 first triennial report provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018.

VI. APPENDICES

Appendix A. Table 2-1. Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

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

Appendix C. Table 5-1-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex/Gender by Race and Ethnicity

Appendix D. Table 2-2. Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between FY2016 and FY2018

Appendix E. Table 5-2-2-C. All Enrollment For NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender, Race, and Ethnicity

Appendix F. NCI Accrual Working Group

APPENDIX A

Table 2-1. Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only*
2016	2,666	294	2,372	2,114	258	391	208	1,773
2017	2,733	331	2,402	2,145	257	405	208	1,789
2018	3,329	465	2,864	2,483	381	552	249	2,063

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

APPENDIX B

Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity¹

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Ethnicity					
						Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown ² Not Reported	% Unknown Not Reported
2016	Female	561,370	10.0	5,630,488	54.3	2,257,542	40.1	189,508	3.4	3,183,438	56.5
2016	Male	372,614	7.9	4,707,527	45.4	1,414,034	30.0	136,656	2.9	3,156,837	67.1
2016	Unknown	10,699	27.6	38,723	0.4	11,153	28.8	1,049	2.7	26,521	68.5
2017	Female	2,271,725	60.4	3,759,860	44.5	3,343,498	88.9	184,035	4.9	232,327	6.2
2017	Male	3,328,218	72.6	4,586,463	54.3	4,271,627	93.1	118,711	2.6	196,125	4.3
2017	Unknown	10,552	10.1	104,304	1.2	11,806	11.3	832	0.8	91,666	87.9
2018	Female	574,047	29.9	1,921,595	58.4	1,576,153	82.0	143,283	7.5	202,159	10.5
2018	Male	248,624	21.3	1,168,054	35.5	999,889	85.6	84,300	7.2	83,865	7.2
2018	Unknown	11,280	5.7	198,198	6.0	11,806	6.0	557	0.3	185,835	93.8

Year	Sex Gender	Race													
		American Indian Alaska Native	% American Indian Alaska Native	Asian ³	% 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
2016	Female	8,289	0.1	185,301	3.3	162,469	2.9	3,832	0.1	2,147,704	38.1	23,184	0.4	3,099,709	55.1
2016	Male	5,867	0.1	103,565	2.2	119,840	2.5	2,992	0.1	1,399,518	29.7	11,488	0.2	3,064,257	65.1
2016	Unknown	28	0.1	9,183	23.7	231	0.6	1	0.0	2,213	5.7	296	0.8	26,771	69.1
2017	Female	8,456	0.2	1,923,906	51.2	139,782	3.7	3,056	0.1	1,521,500	40.5	23,780	0.6	139,380	3.7
2017	Male	5,835	0.1	3,075,798	67.1	117,312	2.6	2,264	0.0	1,264,625	27.6	15,505	0.3	105,124	2.3
2017	Unknown	39	0.0	9,199	8.8	415	0.4	11	0.0	2,238	2.1	117	0.1	92,285	88.5
2018	Female	10,211	0.5	208,329	10.8	189,002	9.8	2,648	0.1	1,286,750	67.0	35,429	1.8	189,226	9.8
2018	Male	4,083	0.3	80,030	6.9	70,791	6.1	1,398	0.1	929,958	79.6	14,286	1.2	67,508	5.8
2018	Unknown	9	0.0	10,273	5.2	172	0.1	10	0.0	1,679	0.8	297	0.1	185,758	93.7

¹The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

APPENDIX C

Table 5-1-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex/Gender by Race and Ethnicity¹

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Ethnicity					
						Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	381,720	10.6	3,607,046	69.5%	2,110,705	58.5	150,501	4.2	1,345,840	37.3
2016	Male	300,509	19.2	1,562,641	30.1%	1,259,444	80.6	131,078	8.4	172,119	11.0
2016	Unknown	1,572	8.5	18,507	0.4%	1,884	10.2	947	5.1	15,676	84.7
2017	Female	309,401	18.1	1,707,496	53.0%	1,426,604	83.5	129,917	7.6	150,975	8.8
2017	Male	268,952	18.8	1,427,887	44.4%	1,124,328	78.7	112,708	7.9	190,851	13.4
2017	Unknown	1,429	1.7	84,126	2.6%	2,535	3.0	730	0.9	80,861	96.1
2018	Female	383,018	23.5	1,627,675	58.0%	1,392,801	85.6	115,342	7.1	119,532	7.3
2018	Male	159,212	15.9	999,533	35.6%	855,932	85.6	65,538	6.6	78,063	7.8
2018	Unknown	1,000	0.6	178,047	6.3%	1,377	0.8	455	0.3	176,206	99.0

Year	Sex Gender	Race													
		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
2016	Female	7,947	0.2	57,757	1.6	149,480	4.1	3,801	0.1	2,057,460	57.0	22,551	0.6	1,308,050	36.3
2016	Male	5,784	0.4	44,094	2.8	112,910	7.2	2,948	0.2	1,301,706	83.3	11,481	0.7	83,718	5.4
2016	Unknown	28	0.2	171	0.9	220	1.2	1	0.0	1,798	9.7	294	1.6	15,995	86.4
2017	Female	8,036	0.5	39,114	2.3	116,724	6.8	3,008	0.2	1,408,637	82.5	22,877	1.3	109,100	6.4
2017	Male	5,693	0.4	31,981	2.2	108,210	7.6	2,202	0.2	1,160,600	81.3	15,320	1.1	103,881	7.3
2017	Unknown	38	0.0	185	0.2	415	0.5	11	0.0	1,813	2.2	110	0.1	81,553	96.9
2018	Female	9,715	0.6	79,301	4.9	157,909	9.7	2,543	0.2	1,178,112	72.4	30,579	1.9	169,516	10.4
2018	Male	3,842	0.4	19,669	2.0	61,182	6.1	1,298	0.1	846,279	84.7	12,944	1.3	54,319	5.4
2018	Unknown	8	0.0	102	0.1	172	0.1	10	0.0	1,253	0.7	291	0.2	176,202	99.0

¹The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

APPENDIX D

Table 2-2. Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between FY2016 and FY2018

Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only*
2016	225	19	206	137	69	48	19	139
2017	242	19	223	148	75	55	16	152
2018	325	30	295	197	98	72	20	203

*Inclusion Data Records (IDRs) 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.

APPENDIX E

Table 5-2-2-C. All Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, by Sex/Gender, Race, and Ethnicity¹

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Ethnicity					
						Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	21,492	37.6	57,150	60.7	44,049	77.1	11,825	20.7	1,276	2.2
2016	Male	10,397	28.1	36,974	39.3	32,719	88.5	3,200	8.7	1,055	2.9
2016	Unknown	0	0.0	69	0.1	1	1.4	0	0.0	68	98.6
2017	Female	23,728	36.7	64,678	58.9	49,999	77.3	12,695	19.6	1,984	3.1
2017	Male	11,879	26.4	45,076	41.0	39,481	87.6	4,141	9.2	1,454	3.2
2017	Unknown	2	2.9	70	0.1	0	0.0	2	2.9	68	97.1
2018	Female	33,897	37.1	91,264	62.5	72,193	79.1	14,921	16.3	4,150	4.5
2018	Male	16,191	29.6	54,662	37.4	47,136	86.2	5,453	10.0	2,073	3.8
2018	Unknown	2	2.7	74	0.1	3	4.1	1	1.4	70	94.6

Year	Sex Gender	Race													
		American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Islander	% Native Hawaiian Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	Female	341	0.6	3,918	6.9	5,393	9.4	78	0.1	37,798	66.1	121	0.2	9,501	16.6
2016	Male	180	0.5	3,815	10.3	3,214	8.7	52	0.1	27,793	75.2	56	0.2	1,854	5.0
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	2	2.9	0	0.0	67	97.1
2017	Female	384	0.6	4,343	6.7	6,277	9.7	153	0.2	43,094	66.6	102	0.2	10,325	16.0
2017	Male	233	0.5	3,160	7.0	4,353	9.7	92	0.2	34,815	77.2	68	0.2	2,355	5.2
2017	Unknown	0	0.0	0	0.0	1	1.4	1	1.4	1	1.4	0	0.0	67	95.7
2018	Female	404	0.4	3,112	3.4	7,318	8.0	245	0.3	59,903	65.6	9,046	9.9	11,236	12.3
2018	Male	303	0.6	1,771	3.2	5,520	10.1	134	0.2	40,418	73.9	3,427	6.3	3,089	5.7
2018	Unknown	0	0.0	0	0.0	0	0.0	1	1.4	3	4.1	1	1.4	69	93.2

¹The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Appendix F

NCI ACCRUAL WORKING GROUP

Division of Extramural Activities (DEA)

Ms. Beth Buschling, Chair
Ms. Clarissa Douglas

Division of Cancer Biology (DCB)

Ms. Michelle Turner

Division of Cancer Control and Population Sciences (DCCPS)

Mr. Mark Alexander
Ms. Gina Tesauro

Division of Cancer Prevention (DCP)

Ms. Cynthia Whitman
Ms. Pamela Maxwell

Division of Cancer Treatment and Diagnosis (DCTD)

Ms. Rolanda Hawkins
Dr. Peter Ujhazy
Ms. Tamara Walton

OD, Cancer Centers Branch (CCB)

Dr. Krzysztof Ptak

OD, Cancer Training Branch (CCT, CTB)

Dr. Jeannette F. Korczak

OD, Center for Strategic Scientific Initiatives (CSSI)

Dr. Mehdi Mesrim

OD, Center to Reduce Cancer Health Disparities (CRCHD)

Dr. Emmanuel Taylor
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