DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

2019 TRIENNIAL ADVISORY COUNCIL REPORTS CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES

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2019 Triennial NIDA Advisory Council Report for Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2016 – FY2018

I. Background/Overview

The mission of the National Institute on Drug Abuse (NIDA) is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health. This involves:

- Strategically supporting and conducting basic and clinical research on drug use (including nicotine), its consequences, and the underlying neurobiological, behavioral, and social mechanisms involved.
- Ensuring the effective translation, implementation, and dissemination of scientific research findings to improve the prevention and treatment of substance use disorders and enhance public awareness of addiction as a brain disorder.

NIDA has a diverse portfolio of grants and contracts with human subjects that fall under the NIH Policy on Inclusion Guidelines. The portfolio includes basic and clinical neuroscience, epidemiology, services, prevention, pharmacotherapies, medical consequences, treatment development, HIV/AIDS, as well as NIH defined phase III clinical trials. These efforts are coordinated by the NIDA Intramural and Extramural programs**.** When it comes to clinical and epidemiological study populations, NIDA's research has always been diverse: Our portfolio by default addresses minority groups who, unfortunately, are often those most affected by consequences and problems related to drug use, including health problems such as HIV/AIDS.

The NIH is mandated by the **Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2** to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

In 1986 NIH established a policy for the inclusion of women in clinical research. This policy stemmed largely from a report of the Public Health Service Task Force on Women's Health in 1985. The policy was initially published in the NIH Guide to Grants

and Contracts in 1987 and then later that year the policy was revised to include language encouraging the inclusion of minorities in clinical studies as well.

To ensure that NIH rigorously implement and enforce the inclusion policy, Congress included in The NIH Revitalization Act of 1993 (Public Law 103-43) a section entitled *Women and Minorities as Subjects in Clinical Research.* In 1994, NIH revised its policies to harmonize with the statutory language. The policy, NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research, can be found at https://grants.nih.gov/grants/funding/women_min/guidelines.htm.

II. Strategies for Ensuring Compliance

NIDA supports the inclusion of a diverse population in clinical studies. Funding announcements contain language requiring that women and minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed. Applicants are encouraged to describe plans to collaborate with other centers to leverage resources for participant diversity and to set specific goals for inclusion of populations with health disparities. NIDA ensures that all applicants, peer reviewers, NIDA scientific review officers, program officers and grants management officers and specialists are aware of the NIH policy on inclusion based on sex/gender, race, ethnicity, and age in clinical research.

A. 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 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.

- NIDA's Office of Extramural Policy and Review (OEPR) does the following:
  - Administer the peer and objective review of all Institute-based extramural grant applications;
  - Administer the concept and peer review of all NIDA research contract proposals;
  - Provide advice and guidance to the Director regarding the Institute's peer and objective review processes;
  - Provide scientific analyses of the Institute's extramural research program, assessing the breadth and scope of the Institute's research activities;
  - Administer the National Advisory Council on Drug Abuse second level review of extramural support mechanisms and advice on overall NIDA program and policy matters;
  - Coordinate and assure the development of program policies and rules relating to the Institute's extramural activities, including Institute responsibility for inquiries and investigations into misconduct in science;
  - Coordinate Institute activities under the Privacy Act;
  - and Administer the Institute's committee management function under the Federal Advisory Committee Act.

B. Program Monitoring and Grants Management Oversight

NIDA ensures that applications are reviewed for compliance with the NIH Policy on Inclusion. 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 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, 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 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.

D. NIDA's Training Approaches

Training at NIDA is a continual process. We rely on NIDA specific training as well as NIH training. The archived online NIDA training on inclusion is available for staff and is a mandatory training requirement. The NIDA inclusion representatives meet with program and data entry staff regularly to ensure compliance with NIH guidelines and to resolve technical issues related to maintaining these data for NIDA. NIDA staff 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. Other training activities include the NIH Extramural Scientist Administrator (ESA) Core Curriculum which provides details on program official responsibilities for protection of Human Subjects.

In June of 2018, the NIH transitioned from the Inclusion Management System (IMS) to the Human Subjects System (HSS), for reporting sex/gender, race, and ethnicity information. The new system is a shared system that enables grant recipients to

electronically report and update their data on human subjects and clinical trials to NIH; and for NIH staff to monitor and manage the data. The HSS is automatically populated by human subjects and clinical trial data entered by the principal investigator (PI) on the Human Subjects and Clinical Trial Information in the applications. This data is then made available to PIs and signing officials through a Human Subjects link that is available on the electronic Research Administration (eRA) Commons Status screen and the Research Performance Progress Report (RPPR). Key changes with the new system are as follows:

- NIH migrated enrollment records in IMS to HSS.
- NIH recipients completing an RPPR will be prompted to access HSS to update inclusion enrollment reports. Recipients may access the system through the Human Subjects link in the RPPR or the eRA Commons Status page.
- *Section 6: Clinical Trial Milestone Plan* is intended for use in progress reports for competing applications submitted on or after January 25, 2018 when noted in the Funding Opportunity Announcement or terms and conditions of award. Recipients should refer to the RPPR Instruction Guide for guidance.
- The HSS system includes a new interface and workflow. When submitting studies to NIH, Signing Officials will submit all study records associated with an application at one time rather than separately.
- Participant-level sex/gender, race, ethnicity and age data may be submitted in a CSV file to populate the Inclusion Enrollment Report. Participant level data is required for applications submitted January 25, 2019 or later. See NOT-OD-18-116 for additional information.
- Investigators and signing officials may make study updates or corrections (including just-in-time or off-cycle updates) by accessing HSS through the Human Subjects link in the eRA Commons Status page. Some changes, including those involving increased risk to human participants, may require prior approval by NIH.
- Users are currently unable to delegate authority for HSS updates and/or submissions to another user. Delegation authority is expected to be available in a future enhancement of HSS.

III. Analysis and Interpretation of Data

Aggregate data for FY 2016–2018 were provided by the NIH Office of Extramural Research (OER) through HSS. The HSS database is the centralized repository for collecting and storing data for all NIH Institutes and Centers (ICs) on human subjects and clinical trials.

Study and enrollment data by sex/gender, ethnicity, and race for clinical research studies are shown in the attached tables. A summary of the data showing percentage of ethnic minorities, and males and females participation for all clinical research is provided here:

Fiscal Year	Minority	Hispanic/Latino	Male	Female	Unknown Sex/Gender
2016	45.0	19.1	48.4	49.6	2.0
2017	34.0	12.7	48.9	47.7	3.4
2018	49.9	17.8	53.8	45.8	0.4

Tables 2-1 and 2-2 capture the number of participants in clinical research studies and Phase III trials as reported by the study principal investigators in the applications. These data are broken down further by race, ethnicity and sex/gender in Table 5-1-1-C.

Aggregate enrollment data for clinical research excluding male-only and female-only inclusion data records (IDRs) are shown in Table 3-1-A respectively. In FY2016, 49.6% were female and 48.3% were male. In FY2017, 47.2% were female and 48.5% were male. In FY2018, 44.0% were female and 52.2% were male.

Human subjects enrolled in NIDA Phase III trials represented 0.05% of NIDA's enrolled subjects in FY2016, 0.46% in FY2017, and 2.1% in FY2018. In FY2016, the data in Table 5-2-2-C attached indicates 52.9% of the volunteers enrolled were minorities and 38.9% were female, 61.0% were male, and 0.1% were unknown sex/gender. The FY2017 data show 56.4% volunteers enrolled were minorities and 35.2% female, 63.9% male and 0.9% unknown sex/gender. The FY2018 data show 55.0% volunteers enrolled were minorities and 34.9% female, 63.5% male and 1.7% unknown sex/gender.

Aggregate enrollment data for NIDA Phase III trials excluding male-only and female-only IDRs are shown in Table 3-3 respectively. In FY2016, 37.6% were female and 60.5%

were male. In FY2017, 32.4% were female and 63.5% were male. In FY2018, 31.5% were female and 63.0% were male.

In increased efforts to validate and clean up the data, and to correctly label existing datasets, the difference in data between years is due to removal of large numbers from the system. Reporting of large cohort studies also ended. One study included all forty years of data collection, when current enrollment is about 45,000 participants. Another study incorrectly included all individuals within a healthcare system (12.7 million) rather than those whose data were included in the study (about 190,000). Revised reports have since been received with the corrected enrollment.

Research, Condition, and Disease Categorization (RCDC) Report

The RCDC Report is used by NIH to inform the public of how tax dollars are being spent on biomedical research within the 27 institutes and centers. RCDC is a computerized process that reports more than 280 categories of diseases, conditions, or research areas. This is the first time this information will be captured in the triennial report on inclusion. The RCDC data will only report on FY 2018 for this reporting period. The data will include IC and NIH totals and median proportions for each category via the website https://report.nih.gov/RISR/#/.

IV. Additional information

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

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/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 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. 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.

B. Relevant Notices from the NIH Guide to Grants and Contracts:

NOT-OD-17-062 – New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-062.html

NOT-OD-18-014 – Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html

NOT-OD-18-116 – Revision: NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html

NOT-OD-18-179 – Transition from Inclusion Management System to the New Human Subjects System (HSS) as of June 9, 2018, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-179.html

Section 2: Metrics Based on Inclusion Data Records (IDRs) - NIDA

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

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	852	83	769	729	40	43	46	680
2017	864	74	790	755	35	51	45	694
2018	901	107	794	742	52	47	65	682

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

Total Inclusion Data Records (IDRs): All NIH-Defined Phase III Trials - NIDA

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

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	110	2	108	105	3	4	3	101
2017	117	2	115	109	6	5	3	107
2018	139	7	132	122	10	7	5	120

*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.

Total Enrollment: All NIH-Defined Clinical Research - NIDA

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

Year	Sex Gender	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
2016	Female	3,715,591	45.4	8,179,737	49.6	115,040	1.4	866,846	10.6	849,383	10.4	108,139	1.3	5,652,109	69.1	221,081	2.7	367,139	4.5	6,369,577	77.9	1,571,387	19.2	238,773	2.9
2016	Male	3,684,100	46.1	7,984,230	48.4	110,631	1.4	877,263	11.0	843,567	10.6	102,379	1.3	5,515,498	69.1	218,988	2.7	315,904	4.0	6,299,886	78.9	1,547,055	19.4	137,289	1.7
2016	Unknown	34,956	10.6	329,869	2.0	583	0.2	823	0.2	5,487	1.7	128	0.0	13,688	4.1	748	0.2	308,412	93.5	150,044	45.5	27,638	8.4	152,187	46.1
2017	Female	313,149	34.6	905,738	47.7	14,018	1.5	32,039	3.5	136,441	15.1	2,417	0.3	562,133	62.1	19,707	2.2	138,983	15.3	752,179	83.0	118,275	13.1	35,284	3.9
2017	Male	323,244	34.9	927,068	48.9	15,596	1.7	33,360	3.6	145,071	15.6	2,729	0.3	571,266	61.6	17,471	1.9	141,575	15.3	771,508	83.2	119,572	12.9	35,988	3.9
2017	Unknown	11,477	17.7	64,911	3.4	827	1.3	839	1.3	4,851	7.5	117	0.2	13,128	20.2	755	1.2	44,394	68.4	21,336	32.9	4,548	7.0	39,027	60.1
2018	Female	108,961	51.0	213,499	45.8	9,593	4.5	7,441	3.5	51,527	24.1	1,379	0.6	113,513	53.2	7,986	3.7	22,060	10.3	162,877	76.3	38,709	18.1	11,913	5.6
2018	Male	127,162	50.7	251,018	53.8	9,727	3.9	10,053	4.0	62,839	25.0	1,302	0.5	129,773	51.7	8,045	3.2	29,279	11.7	196,627	78.3	44,126	17.6	10,265	4.1
2018	Unknown	298	14.4	2,066	0.4	26	1.3	15	0.7	106	5.1	0	0.0	231	11.2	44	2.1	1,644	79.6	848	41.0	138	6.7	1,080	52.3

Total Enrollment: All NIH-Defined Clinical Research - NIDA

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

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	3,715,591	45.4	8,179,737	49.6	6,369,577	77.9	1,571,387	19.2	238,773	2.9
2016	Male	3,684,100	46.1	7,984,230	48.4	6,299,886	78.9	1,547,055	19.4	137,289	1.7
2016	Unknown	34,956	10.6	329,869	2.0	150,044	45.5	27,638	8.4	152,187	46.1
2017	Female	313,149	34.6	905,738	47.7	752,179	83.0	118,275	13.1	35,284	3.9
2017	Male	323,244	34.9	927,068	48.9	771,508	83.2	119,572	12.9	35,988	3.9
2017	Unknown	11,477	17.7	64,911	3.4	21,336	32.9	4,548	7.0	39,027	60.1
2018	Female	108,961	51.0	213,499	45.8	162,877	76.3	38,709	18.1	11,913	5.6
2018	Male	127,162	50.7	251,018	53.8	196,627	78.3	44,126	17.6	10,265	4.1
2018	Unknown	298	14.4	2,066	0.4	848	41.0	138	6.7	1,080	52.3

Year	Sex Gender	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	115,040	1.4	866,846	10.6	849,383	10.4	108,139	1.3	5,652,109	69.1	221,081	2.7	367,139	4.5
2016	Male	110,631	1.4	877,263	11.0	843,567	10.6	102,379	1.3	5,515,498	69.1	218,988	2.7	315,904	4.0
2016	Unknown	583	0.2	823	0.2	5,487	1.7	128	0.0	13,688	4.1	748	0.2	308,412	93.5
2017	Female	14,018	1.5	32,039	3.5	136,441	15.1	2,417	0.3	562,133	62.1	19,707	2.2	138,983	15.3
2017	Male	15,596	1.7	33,360	3.6	145,071	15.6	2,729	0.3	571,266	61.6	17,471	1.9	141,575	15.3
2017	Unknown	827	1.3	839	1.3	4,851	7.5	117	0.2	13,128	20.2	755	1.2	44,394	68.4
2018	Female	9,593	4.5	7,441	3.5	51,527	24.1	1,379	0.6	113,513	53.2	7,986	3.7	22,060	10.3
2018	Male	9,727	3.9	10,053	4.0	62,839	25.0	1,302	0.5	129,773	51.7	8,045	3.2	29,279	11.7
2018	Unknown	26	1.3	15	0.7	106	5.1	0	0.0	231	11.2	44	2.1	1,644	79.6

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

Section 3: Metrics Based on Aggregate Enrollment: Sex/Gender - NIDA

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018 - NIDA

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male- only	% Males, Excluding Male- only
2016	16,493,836	8,179,737	49.6	7,984,230	48.4	329,869	2.0	6,634	0.0	15,706	0.1	8,173,103	49.6	7,968,524	48.3
2017	1,897,717	905,738	47.7	927,068	48.9	64,911	3.4	10,727	0.6	6,628	0.3	895,011	47.2	920,440	48.5
2018	466,583	213,499	45.8	251,018	53.8	2,066	0.4	8,341	1.8	7,443	1.6	205,158	44.0	243,575	52.2

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 Phase III Trials - NIDA

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Trials, Sex/Gender by Race and Ethnicity - NIDA

Year	Sex Gender	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
2016	Female	1,876	54.6	3,438	38.9	49	1.4	94	2.7	1,292	37.6	4	0.1	1,633	47.5	169	4.9	197	5.7	3,076	89.5	341	9.9	21	0.6
2016	Male	2,831	52.5	5,392	61.0	46	0.9	114	2.1	1,829	33.9	6	0.1	2,748	51.0	227	4.2	422	7.8	4,665	86.5	718	13.3	9	0.2
2016	Unknown	4	57.1	7	0.1	0	0.0	0	0.0	2	28.6	0	0.0	0	0.0	2	28.6	3	42.9	7	100.0	0	0.0	0	0.0
2017	Female	2,162	56.9	3,798	35.2	50	1.3	115	3.0	1,526	40.2	4	0.1	1,562	41.1	182	4.8	359	9.5	3,387	89.2	390	10.3	21	0.6
2017	Male	3,337	48.4	6,901	63.9	46	0.7	471	6.8	1,947	28.2	4	0.1	2,688	39.0	238	3.4	1,507	21.8	6,154	89.2	741	10.7	6	0.1
2017	Unknown	3	3.1	96	0.9	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	1	1.0	93	96.9	95	99.0	0	0.0	1	1.0
2018	Female	2,481	47.3	5,242	34.9	53	1.0	146	2.8	1,782	34.0	6	0.1	1,934	36.9	194	3.7	1,127	21.5	4,798	91.5	408	7.8	36	0.7
2018	Male	3,135	32.9	9,542	63.5	50	0.5	200	2.1	1,974	20.7	5	0.1	3,189	33.4	246	2.6	3,878	40.6	8,743	91.6	776	8.1	23	0.2
2018	Unknown	10	4.0	250	1.7	0	0.0	0	0.0	6	2.4	0	0.0	22	8.8	1	0.4	221	88.4	245	98.0	3	1.2	2	0.8

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 Phase III Trials - NIDA

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Trials, S

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	1,876	54.6	3,438	38.9	3,076	89.5	341	9.9	21	0.6
2016	Male	2,831	52.5	5,392	61.0	4,665	86.5	718	13.3	9	0.2
2016	Unknown	4	57.1	7	0.1	7	100.0	0	0.0	0	0.0
2017	Female	2,162	56.9	3,798	35.2	3,387	89.2	390	10.3	21	0.6
2017	Male	3,337	48.4	6,901	63.9	6,154	89.2	741	10.7	6	0.1
2017	Unknown	3	3.1	96	0.9	95	99.0	0	0.0	1	1.0
2018	Female	2,481	47.3	5,242	34.9	4,798	91.5	408	7.8	36	0.7
2018	Male	3,135	32.9	9,542	63.5	8,743	91.6	776	8.1	23	0.2
2018	Unknown	10	4.0	250	1.7	245	98.0	3	1.2	2	0.8

Year	Sex Gender	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	49	1.4	94	2.7	1,292	37.6	4	0.1	1,633	47.5	169	4.9	197	5.7
2016	Male	46	0.9	114	2.1	1,829	33.9	6	0.1	2,748	51.0	227	4.2	422	7.8
2016	Unknown	0	0.0	0	0.0	2	28.6	0	0.0	0	0.0	2	28.6	3	42.9
2017	Female	50	1.3	115	3.0	1,526	40.2	4	0.1	1,562	41.1	182	4.8	359	9.5
2017	Male	46	0.7	471	6.8	1,947	28.2	4	0.1	2,688	39.0	238	3.4	1,507	21.8
2017	Unknown	0	0.0	0	0.0	2	2.1	0	0.0	0	0.0	1	1.0	93	96.9
2018	Female	53	1.0	146	2.8	1,782	34.0	6	0.1	1,934	36.9	194	3.7	1,127	21.5
2018	Male	50	0.5	200	2.1	1,974	20.7	5	0.1	3,189	33.4	246	2.6	3,878	40.6
2018	Unknown	0	0.0	0	0.0	6	2.4	0	0.0	22	8.8	1	0.4	221	88.4

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 Phase III Trials – NIDA

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	8,837	3,438	38.9	5,392	61.0	7	0.1	117	1.3	50	0.6	3,321	37.6	5,342	60.5
2017	10,795	3,798	35.2	6,901	63.9	96	0.9	297	2.8	50	0.5	3,501	32.4	6,851	63.5
2018	15,034	5,242	34.9	9,542	63.5	250	1.7	502	3.3	77	0.5	4,740	31.5	9,465	63.0

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