


2022 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 FY2019 – FY2021

I. Background/Overview

The National Institute on Drug Abuse (NIDA) is the lead federal agency supporting scientific research on drug use and its consequences. The mission of 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 policy to harmonize it 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. The NIDA Advisory Council performs the second level of review and makes recommendations for funding to the NIDA Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NIDA. 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

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 requirements for plans and reporting of 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 Grant 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/gender, race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed and plans to increase recruitment are 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.

D. NIDA's Training Approaches

Training at NIDA is a continual process. The NIDA inclusion representatives meet with program staff as needed to ensure compliance with NIH guidelines and to resolve technical issues related to maintaining these data for NIDA. NIDA's Program Officials/Program Directors and Scientific Review Officers attended the 2020 Inclusion Training for Program Staff and the 2020 Inclusion Training for Review Staff in April 2020. 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.

III. Analysis and Interpretation of Data

Aggregate data for FY 2019–2021 were provided by the NIH Office of Extramural Research (OER) through the Human Subjects System (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 the percentage of ethnic minorities, and males and females, among all clinical research participants is provided here:

Fiscal Year	Minority	Hispanic/Latino	Male	Female	Unknown Sex/Gender
2019	33.6	9.5	56.1	43.2	0.7
2020	27.4	8.9	53.6	45.9	0.4
2021	42.5	17.5	49.5	45.9	4.6

In Tables 2-1 and 2-2, the total inclusion enrollment reports (IERs) capture the number of participants in clinical research studies and Phase III trials as reported by the study principal investigators. The total enrollment in FY2019 was 1,677,246, in FY2020 2,220,107 and in FY2021 355,144. Table 2-3 includes the total IERs that required a valid analysis by sex/gender and race/ethnicity. In FY2019, the total IERs for NIDA Phase III

trials were 169, in FY2020 there were 59, and in FY2021 there were 70. 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 IERs are shown in Table 3-1-A respectively. In FY2019, 42.3% were female and 55.9% were male. In FY2020, 45.4% were female and 53.6% were male. In FY2021, 44.4% were female and 48.6% were male. The data in Table 4-1-2-D indicate minority participants represented 33.6% in FY2019, 27.4% in FY2020, and 42.5% in FY2021.

Participants enrolled in NIDA Phase III trials represented 0.65% of NIDA's total enrolled participants in FY2019, 0.11% in FY2020, and 3.4% in FY2021. In FY2019, data in Tables 4-2-2-D and 5-2-2-C indicate that 52.5% of the volunteers enrolled were minorities and 24.7% were female, 43.8% were male, and 31.5% were of unknown sex/gender. The FY2020 data show that 43.5% of volunteers enrolled were minorities and 42.4% female, 52.4% male and 5.1% of unknown sex/gender. The FY2021 data show that 51.2% of volunteers enrolled were minorities and 37.5% female, 58.9% male and 3.6% of 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 FY2019, 24.0% were female and 43.4% were male. In FY2020, 41.2% were female and 52.4% were male. In FY2021, 36.7% were female and 58.9% were male.

NIDA has been making efforts to validate and clean the data, and to correctly label existing datasets. In FY2019 and FY2020, there were existing datasets incorrectly labelled as prospective data, and this was corrected in FY2021. The difference in data between years is due to removal of those large numbers from the system.

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 to support 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. The RCDC data will only report on FY2018. The data will include IC and NIH totals and median proportions for each category via the website

<https://report.nih.gov/RISR/#/>.

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 Fiscal Years 2019 and 2021

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*
2019	1,282	427	855	797	58	51	40	764
2020	1,187	566	621	587	34	55	25	541
2021	1,378	688	690	659	31	66	37	587

*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 Fiscal Years 2019 and 2021

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*
2019	169	29	140	129	11	5	4	131
2020	59	38	21	19	2	3	1	17
2021	70	31	39	38	1	9	0	30

*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 Phase III Clinical Trials

Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERS	IERS Requiring Race Ethnicity Valid Analysis	% IERS Requiring Race Ethnicity Valid Analysis	IERS Requiring Sex Gender Valid Analysis	% IERS Requiring Sex Gender Valid Analysis
2019	169	168	99.4	168	99.4
2020	59	58	98.3	58	98.3
2021	70	70	100.0	70	100.0

Current methodology to monitor valid analysis began in 2019 and differs from what was used in 2018 (N/A in 2018). Plans for valid analysis methodologies specified in the project application are reported for all IERS, including IERS that have no reported actual enrollment at the time of reporting.

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

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2019 and 2021

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
2019	1,677,246	723,782	43.2	941,502	56.1	11,962	0.7	13,484	0.8	3,903	0.2	710,298	42.3	937,599	55.9
2020	2,220,107	1,019,700	45.9	1,191,052	53.6	9,355	0.4	11,213	0.5	1,296	0.1	1,008,487	45.4	1,189,756	53.6
2021	355,144	163,142	45.9	175,829	49.5	16,173	4.6	5,568	1.6	3,269	0.9	157,574	44.4	172,560	48.6

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 3-1-B. Total Enrollment for All NIH-Defined Extramural Clinical Research Between Fiscal Years 2019 and 2021

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
2019	1,673,145	722,113	43.2	939,071	56.1	11,961	0.7	13,483	0.8	3,903	0.2	708,630	42.4	935,168	55.9
2020	2,215,911	1,018,007	45.9	1,188,556	53.6	9,348	0.4	11,211	0.5	1,296	0.1	1,006,796	45.4	1,187,260	53.6
2021	351,081	161,508	46.0	173,406	49.4	16,167	4.6	5,568	1.6	3,269	0.9	155,940	44.4	170,137	48.5

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 3-1-C. Total Enrollment for All NIH-Defined Intramural Clinical Research Between Fiscal Years 2019 and 2021

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
2019	4,101	1,669	40.7	2,431	59.3	1	0.0	1	0.0	0	0.0	1,668	40.7	2,431	59.3
2020	4,196	1,693	40.3	2,496	59.5	7	0.2	2	0.0	0	0.0	1,691	40.3	2,496	59.5
2021	4,063	1,634	40.2	2,423	59.6	6	0.1	0	0.0	0	0.0	1,634	40.2	2,423	59.6

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

Total Enrollment: All NIH-Defined Phase III Trials

Table 3-3. Total Enrollment for All NIH-Defined Phase III Trials Reporting Between Fiscal Years 2019 and 2021

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
2019	21,218	5,242	24.7	9,285	43.8	6,691	31.5	158	0.7	85	0.4	5,084	24.0	9,200	43.4
2020	3,234	1,372	42.4	1,696	52.4	166	5.1	38	1.2	3	0.1	1,334	41.2	1,693	52.4
2021	12,699	4,763	37.5	7,477	58.9	459	3.6	106	0.8	0	0.0	4,657	36.7	7,477	58.9

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 4: US Site Minority Enrollment

Table 4-1-2-D. Total US Site Enrollment of NIH-Defined Clinical Research

Fiscal Year	Total Enrollees	Minority Enrollees	% Minority Enrollees
2019	1,627,809	546,937	33.6
2020	2,190,652	599,180	27.4
2021	333,498	141,811	42.5

Table 4-2-2-D. US Site Enrollment of NIH-Defined Phase III Trials

Fiscal Year	Total Enrollees	Minority Enrollees	% Minority Enrollees
2019	10,931	5,740	52.5
2020	2,644	1,149	43.5
2021	12,170	6,234	51.2

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

Section 6: Enrollment by Ethnicity

Table 4-1-1-D. Total Enrollment of All NIH-Defined Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	1,486,360	88.6	160,074	9.5	30,812	1.8
2020	1,793,042	80.8	198,150	8.9	228,915	10.3
2021	267,366	75.3	62,246	17.5	25,532	7.2

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

Table 4-1-1-E. Total Enrollment of All NIH-Defined Extramural Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	1,482,514	88.6	159,924	9.6	30,707	1.8
2020	1,789,142	80.7	197,994	8.9	228,775	10.3
2021	263,589	75.1	62,105	17.7	25,387	7.2

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

Table 4-1-1-F. Total Enrollment of All NIH-Defined Intramural Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	3,846	93.8	150	3.7	105	2.6
2020	3,900	92.9	156	3.7	140	3.3
2021	3,777	93.0	141	3.5	145	3.6

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

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

Fiscal 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 Islander	% Native Hawaiian Islander	White	% White
2019	Female	241,427	33.4	723,782	43.2	15,497	2.1	15,178	2.1	120,836	16.7	2,421	0.3	505,052	69.8
2019	Male	334,804	35.6	941,502	56.1	17,142	1.8	23,500	2.5	205,999	21.9	3,076	0.3	630,668	67.0
2019	Unknown	1,293	10.8	11,962	0.7	96	0.8	99	0.8	357	3.0	15	0.1	824	6.9
2020	Female	271,752	26.7	1,019,700	45.9	14,053	1.4	27,809	2.7	118,842	11.7	2,102	0.2	650,473	63.8
2020	Male	349,616	29.4	1,191,052	53.6	14,659	1.2	36,178	3.0	196,180	16.5	2,588	0.2	745,105	62.6
2020	Unknown	1,828	19.5	9,355	0.4	241	2.6	122	1.3	451	4.8	20	0.2	1,315	14.1
2021	Female	69,752	42.8	163,142	45.9	3,777	2.3	6,534	4.0	25,260	15.5	615	0.4	101,850	62.4
2021	Male	83,228	47.3	175,829	49.5	3,582	2.0	11,391	6.5	33,427	19.0	719	0.4	100,282	57.0
2021	Unknown	2,252	13.9	16,173	4.6	161	1.0	237	1.5	555	3.4	27	0.2	2,694	16.7

Fiscal Year	Sex Gender	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
2019	Female	21,065	2.9	43,733	6.0	631,242	87.2	78,364	10.8	14,176	2.0
2019	Male	17,111	1.8	44,006	4.7	846,882	90.0	81,030	8.6	13,590	1.4
2019	Unknown	222	1.9	10,349	86.5	8,236	68.9	680	5.7	3,046	25.5
2020	Female	18,837	1.8	187,584	18.4	804,894	78.9	100,614	9.9	114,192	11.2
2020	Male	13,655	1.1	182,687	15.3	986,103	82.8	96,657	8.1	108,292	9.1
2020	Unknown	351	3.8	6,855	73.3	2,045	21.9	879	9.4	6,431	68.7
2021	Female	7,996	4.9	17,110	10.5	126,726	77.7	29,776	18.3	6,640	4.1
2021	Male	7,593	4.3	18,835	10.7	136,913	77.9	31,361	17.8	7,555	4.3
2021	Unknown	385	2.4	12,114	74.9	3,727	23.0	1,109	6.9	11,337	70.1

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

All Enrollment: All NIH-Defined Clinical Research

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

Fiscal 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
2019	Female	2,503	47.7	5,242	24.7	66	1.3	191	3.6	1,702	32.5	10	0.2	2,462	47.0
2019	Male	3,757	40.5	9,285	43.8	58	0.6	387	4.2	2,318	25.0	8	0.1	4,062	43.7
2019	Unknown	9	0.1	6,691	31.5	0	0.0	0	0.0	6	0.1	0	0.0	19	0.3
2020	Female	563	41.0	1,372	42.4	10	0.7	13	0.9	473	34.5	4	0.3	807	58.8
2020	Male	595	35.1	1,696	52.4	6	0.4	13	0.8	508	30.0	3	0.2	592	34.9
2020	Unknown	1	0.6	166	5.1	0	0.0	0	0.0	0	0.0	0	0.0	4	2.4
2021	Female	2,319	48.7	4,763	37.5	66	1.4	191	4.0	1,431	30.0	15	0.3	2,533	53.2
2021	Male	4,443	59.4	7,477	58.9	80	1.1	481	6.4	2,525	33.8	12	0.2	3,135	41.9
2021	Unknown	1	0.2	459	3.6	0	0.0	0	0.0	0	0.0	0	0.0	5	1.1

Fiscal Year	Sex Gender	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
2019	Female	212	4.0	599	11.4	4,777	91.1	410	7.8	55	1.0
2019	Male	277	3.0	2,175	23.4	8,174	88.0	840	9.0	271	2.9
2019	Unknown	1	0.0	6,665	99.6	6,672	99.7	2	0.0	17	0.3
2020	Female	27	2.0	38	2.8	1,267	92.3	56	4.1	49	3.6
2020	Male	27	1.6	547	32.3	1,104	65.1	54	3.2	538	31.7
2020	Unknown	1	0.6	161	97.0	6	3.6	0	0.0	160	96.4
2021	Female	61	1.3	466	9.8	4,070	85.5	669	14.0	24	0.5
2021	Male	43	0.6	1,201	16.1	5,940	79.4	1,524	20.4	13	0.2
2021	Unknown	0	0.0	454	98.9	6	1.3	1	0.2	452	98.5

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

Fiscal 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
2019	Female	2,503	47.7	5,242	24.7	66	1.3	191	3.6	1,702	32.5	10	0.2	2,462	47.0
2019	Male	3,757	40.5	9,285	43.8	58	0.6	387	4.2	2,318	25.0	8	0.1	4,062	43.7
2019	Unknown	9	0.1	6,691	31.5	0	0.0	0	0.0	6	0.1	0	0.0	19	0.3
2020	Female	563	41.0	1,372	42.4	10	0.7	13	0.9	473	34.5	4	0.3	807	58.8
2020	Male	595	35.1	1,696	52.4	6	0.4	13	0.8	508	30.0	3	0.2	592	34.9
2020	Unknown	1	0.6	166	5.1	0	0.0	0	0.0	0	0.0	0	0.0	4	2.4
2021	Female	2,319	48.7	4,763	37.5	66	1.4	191	4.0	1,431	30.0	15	0.3	2,533	53.2
2021	Male	4,443	59.4	7,477	58.9	80	1.1	481	6.4	2,525	33.8	12	0.2	3,135	41.9
2021	Unknown	1	0.2	459	3.6	0	0.0	0	0.0	0	0.0	0	0.0	5	1.1

Fiscal Year	Sex Gender	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
2019	Female	212	4.0	599	11.4	4,777	91.1	410	7.8	55	1.0
2019	Male	277	3.0	2,175	23.4	8,174	88.0	840	9.0	271	2.9
2019	Unknown	1	0.0	6,665	99.6	6,672	99.7	2	0.0	17	0.3
2020	Female	27	2.0	38	2.8	1,267	92.3	56	4.1	49	3.6
2020	Male	27	1.6	547	32.3	1,104	65.1	54	3.2	538	31.7
2020	Unknown	1	0.6	161	97.0	6	3.6	0	0.0	160	96.4
2021	Female	61	1.3	466	9.8	4,070	85.5	669	14.0	24	0.5
2021	Male	43	0.6	1,201	16.1	5,940	79.4	1,524	20.4	13	0.2
2021	Unknown	0	0.0	454	98.9	6	1.3	1	0.2	452	98.5

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 5-2-4-C. All Enrollment for NIH-Defined Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal 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
2019	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2019	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2019	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Fiscal Year	Sex Gender	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
2019	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2019	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2019	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2020	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2021	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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