

Compliance with the NIH Policy on the Inclusion of Women and Minorities in Clinical Research: National Institute on Alcohol Abuse and Alcoholism

Background

The mission of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is to generate and disseminate fundamental knowledge about the adverse effects of alcohol on health and well-being, and apply that knowledge to improve diagnosis, prevention, and treatment of alcohol-related problems, including alcohol use disorder (AUD), across the lifespan.

NIAAA supports and conducts research on the negative impact of alcohol use on human health and well-being through its extramural and intramural research programs. It is the largest funder of alcohol research in the world.

NIAAA leads the national effort to reduce alcohol-related problems by:

- Conducting and supporting a portfolio of alcohol-related research in a wide range of scientific areas including neuroscience and behavior, epidemiology and prevention, treatment and recovery, and metabolism and health effects.
- Coordinating and collaborating with other research institutes and federal programs on alcohol-related issues.
- Collaborating with international, national, state, and local institutions, organizations, agencies, and programs engaged in alcohol-related work.
- Translating and disseminating research findings to health care providers, researchers, policymakers, and the public.

NIAAA-funded discoveries have important implications for improving the health and well-being of all people. For more information about NIAAA's research priorities, visit

<https://www.niaaa.nih.gov/strategic-plan>

NIAAA Strategies for Ensuring Compliance with the NIH Inclusion Policy

Peer Review

The implementation of the NIH inclusion policy involves the participation of review, program, science policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels, also known as scientific review groups (SRG), are given

specific guidance¹ on reviewing inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research² applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion. For NIH-defined Phase III clinical trials,³ enrollment goals are further assessed for plans to conduct analyses of intervention effects among women and racial and ethnic groups. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the minutes of the review session. SRGs make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, program staff notify principal investigators, who are required to address these issues prior to funding. The National Advisory Council on Alcohol Abuse and Alcoholism performs the second level of review and makes recommendations for funding to the NIAAA Director considering the overall impact score, percentile ranking, and summary statement considering the research priorities for NIAAA. Applications with unacceptable inclusion plans receive a bar to funding. An award is not issued until an acceptable resolution is received from the principal investigators.

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 submitted in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors monitor requirements for plans and reporting of sex and race/ethnicity analyses in applications and annual progress reports. Grants management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file.

Intramural Research

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 Institutional Review Board (IRB) review and renewal, the investigator documents the number, sex, and race and ethnicity of participants who were recruited during the past year. Any issues with the accrual of participants are addressed, and the plan to increase recruitment is reviewed by both the Institute and the pertinent IRB. The Clinical Center's Office of Protocol Services coordinates annual reporting of demographic participant data to the NIH Office of Extramural Research and the NIH Office of Research on Women's Health.

¹ See "Guidelines for the Review of Inclusion on the Basis of Sex, Race, Ethnicity, and Age in Clinical Research," https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_subjects_Inclusion.pdf

² <https://grants.nih.gov/grants/glossary.htm#ClinicalResearch>

³ <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition>

NIAAA Staff Training

NIAAA program officials/directors, scientific review officers, grants management, and science policy staff attended inclusion training, including training on the NIH Human Subjects System, in January 2022. Staff may access the archived training on the NIH staff intranet.

NIAAA Aggregate Inclusion Data for Fiscal Years (FY) 2022, FY 2023, and FY 2024: Analysis and Interpretation

Overview

Tables 1-10 include NIAAA aggregate inclusion data and are include in the Appendix of this report. A brief analysis of the data is below.

Table 1 shows the number of NIAAA-supported intramural and extramural inclusion enrollment records (IERs) during the reporting period. IERs are required for all studies involving NIH-defined clinical research, including research conducted at foreign sites. IERs are used to report both planned and cumulative (or actual) enrollment and describe the sex, race, and ethnicity of the study participants. The number of IERs was relatively stable over the reporting period. NIAAA supported 674, 667, and 650 IERs in FYs 2022, 2023 and 2024, respectively.

Tables 2-4 display the enrollment for all NIH-defined clinical research by sex, race, and ethnicity for FYs 2022, 2023 and 2024. The total enrollment was 142,428 participants in FY 2022, 139,149 participants in FY 2023, and 557,734 participants in FY 2024 (Table 2). The enrollment consisted primarily of IERs with less than 1,000 participants with various sex, race, and ethnicity distributions. In each fiscal year, however, a study with a large sample size (i.e. greater than 50,000 participants) reported data that significantly increased enrollment for specific categories and affected the distributions of the aggregate data for the fiscal year. Specifically, one study with 66,499 participants impacted certain enrollment categories in FY 2022 and in FY 2023. A study with 438,020 participants impacted certain enrollment categories in FY 2024.

Tables 5-7 display sex enrollment by race and ethnicity for NIAAA-supported clinical research. Tables 8-10 display data for NIH-defined Phase III clinical trials only.

Enrollment by Sex

The proportion of females and males across the reporting period remained relatively stable (56 to 52 percent female participants) as shown in Table 2. For each fiscal year, the values in parentheses reflect the percentages after excluding a large study with a sample size >50,000 participants (54 to 51 percent female participants). The large studies described above did not significantly affect the overall proportion of males and females in the enrollment data.

Enrollment by Race and Ethnicity

Table 3 shows the NIAAA enrollment for all NIH-defined clinical research by race and Table 4 shows enrollment by ethnicity. In FY 2024, a large study (483,020 participants) reported an enrollment with a high proportion of Asian participants and participants with unknown/not reported race and ethnicity, skewing the overall data for these categories (see also Table 7). To demonstrate the impact of the two studies on the aggregate percentages, values in parentheses that reflect the percentages after excluding the two large studies (>50,000 participants). When the large studies are excluded, enrollment in these two race categories is more stable across the reporting period. Enrollment of Hispanic participants was 11.2 percent in FY 2022, 8.7 percent in FY 2023, and 10.4 percent in FY 2024 (Table 4).

Phase III Clinical Trials

NIAAA supports very few Phase III clinical trials; therefore, enrollment in these studies represents a small fraction of the total NIAAA clinical research enrollment (Tables 8-10). There was fluctuation among sex and certain race categories during the reporting period for various reasons. These reasons include: different studies reported enrollment in each fiscal year, studies had a high enrollment of a specific sex, and/or study sites were in countries with either high or low minority representation. For example, in FY 2024, a study enrolled participants exclusively from Kenya and Uganda, thus significantly increasing the percentage of Black/African American enrollment that year.

Summary

In summary, noticeable shifts in certain race categories occurred during the reporting period. While it is not uncommon for fluctuations to occur with turnover of grant awards, several large changes were observed that were attributed to two studies that reported large sample sizes which resulted in skewing of the distribution of enrollment percentages. NIAAA will continue to closely monitor its enrollment numbers and work with grantees to ensure accurate reporting and compliance with the NIH inclusion guidelines.

An alternative way to view NIAAA inclusion data is by NIH [Research, Condition, and Disease Categorization](https://report.nih.gov/RISR/) (RCDC) areas. NIAAA inclusion data by sex, race, and ethnicity and by age groups for NIH research, condition, and disease funding categories are available at <https://report.nih.gov/RISR/>.

Appendix: NIAAA Aggregate Inclusion Data Tables FY 2022, FY 2023, and FY 2024

Table 1. Total Inclusion Data Records for NIH-Defined Extramural and Intramural Clinical Research, FY 2022, FY 2023, and FY 2024

	FY 2022	FY 2023	FY 2024
US Site	327	304	317
Non-US Site	28	26	28
Female Only	19	21	15
Male Only	17	19	11
Excluding Male-only & Female-only*	319	290	319
Without Enrollment	319	337	305
With Enrollment	355	330	345
Total	674	667	650

*Inclusion Data Records excluding male-only and female-only include unknown sex and combination of unknown and any sex

Table 2. NIAAA Enrollment for All NIH-Defined Clinical Research by Sex

Sex	FY 2022	FY 2023	FY 2024
Female	79,791	78,518	287,707
%	56.0 (53.8)	56.4 (54.4)	51.6 (51.0)
Male	61,724	59,454	268,757
%	43.3 (45.0)	42.7 (44.0)	48.2 (47.6)
Unknown	913	1,177	1,270
%	0.6 (1.2)	0.8 (1.6)	0.2 (1.4)
Total Enrollment	142,428	139,149	557,734

Percentages in parentheses exclude studies with enrollment greater than 50,000 participants. In FY 2022 and FY 2023, there was one study with 66,499 participants, and in FY 2024, there was one study with 438,020 participants.

Table 3. NIAAA Enrollment for All NIH-Defined Clinical Research by Race

Race	FY 2022	FY 2023	FY 2024
American Indian/Alaska Native	2,425	1,789	3,278
%	1.6 (2.3)	1.3 (1.8)	0.6 (2.4)
Asian	10,810	10,772	123,476
%	7.6 (5.9)	7.7 (6.1)	22.1 (4.5)
Black/African American	17,671	17,693	73,117
%	12.4 (19.1)	12.7 (20.0)	13.1 (20.0)
Native Hawaiian/Pacific Islander	1,705	1,681	2,452
%	1.2 (1.4)	1.2 (1.5)	0.4 (1.6)
White	92,879	89,284	227,118
%	65.2 (59.2)	64.2 (56.9)	66.9 (61.6)
More Than One Race	4,854	4,677	16,674
%	3.4 (3.9)	3.4 (3.8)	3.0 (4)
Unknown/Not Reported	12,264	13,253	111,619
%	8.6 (8.2)	9.5 (9.9)	20.0 (5.9)
Total Enrollment	142,428	139,149	557,734

Percentages in parentheses exclude studies with enrollment greater than 50,000 participants. In FY 2022 and FY 2023, there was one study with 66,499 participants, and in FY 2024, there was one study with 438,020 participants.

Table 4. NIAAA Enrollment for All NIH-Defined Clinical Research by Ethnicity

Ethnicity	FY 2022	FY 2023	FY 2024
Not Hispanic	120,235	118,251	186,081
%	89.4 (80.6)	90.6 (85.6)	86.5 (84.1)
Hispanic/Latino	15,908	13,888	81,649
%	11.2 (15.7)	8.7 (11.9)	10.4 (15)
Unknown/Not Reported	6,285	7,010	290,004
%	4.4 (3.7)	0.7 (2.5)	3.1 (0.9)
Total Enrollment	142,428	139,149	557,734

Percentages in parentheses exclude studies with enrollment greater than 50,000 participants. In FY 2022 and FY 2023, there was one study with 66,499 participants, and in FY 2024, there was one study with 438,020 participants.

Table 5. NIAAA Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity, FY 2022

	Female	Male	Unknown	Totals
Total Enrollment	79,791	61,724	913	142,428
%	56.0	43.3	0.6	-
Total Minority Enrollment	29,039	21,298	305	50,642
%	36.4	34.5	33.4	35.6
By Race	Female	Male	Unknown	Totals
American Indian/Alaska Native	1,499	737	9	2,245
%	1.9	1.2	1.0	1.6
Asian	6,516	4,263	31	10,810
%	8.2	6.9	3.4	7.6
Black/African American	9,702	7,924	45	17,671
%	12.2	12.8	4.9	12.4
Native Hawaiian/Pacific Islander	1,242	459	4	1,705
%	1.6	0.7	0.4	1.2
White	51,699	40,708	472	92,879
%	64.8	66.0	51.7	65.2
More Than One Race	2,996	1,737	121	4,854
%	3.8	2.8	13.3	3.4
Unknown/Not Reported	6,137	5,896	231	12,264
%	7.7	9.6	25.3	8.6
By Ethnicity	Female	Male	Unknown	Totals
Not Hispanic	68,219	51,449	567	120,235
%	85.5	83.4	62.1	84.4
Hispanic/Latino	8,636	7,106	166	15,908
%	10.8	11.5	18.2	11.2
Unknown/Not Reported	2,936	3,169	166	6,285
%	3.7	5.1	19.7	4.4

Table 6. NIAAA Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity, FY 2023

	Female	Male	Unknown	Totals
Total Enrollment	78,518	59,454	1,177	139,149
%	56.4	42.7	0.8	-
Total Minority Enrollment	27,634	19,993	322	47,949
%	35.2	33.6	27.4	34.5
By Race	Female	Male	Unknown	Totals
American Indian/Alaska Native	1,091	686	12	1,789
%	1.4	1.2	1.0	1.3
Asian	6,428	4,312	32	10,772
%	8.2	7.3	2.7	7.7
Black/African American	9,873	7,769	51	17,693
%	12.6	13.1	4.3	12.7
Native Hawaiian/Pacific Islander	1266	407	8	1,681
%	1.6	0.7	0.7	1.2
White	50,533	38,256	495	89,284
%	64.4	64.3	42.1	64.2
More Than One Race	2,796	1,757	124	4,677
%	3.6	3.0	10.5	3.4
Unknown/Not Reported	6,535	6,267	455	13,253
%	8.3	10.5	38.7	9.5
By Ethnicity	Female	Male	Unknown	Totals
Not Hispanic	67,618	50,006	627	118,251
%	86.1	84.1	53.3	85.0
Hispanic/Latino	7,698	6,023	53.3	13,888
%	9.8	10.1	14.2	10.0
Unknown/Not Reported	3,202	3,425	383	7,010
%	4.1	5.8	32.5	5.0

Table 7. NIAAA Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity, FY 2024

	Female	Male	Unknown	Totals
Total Enrollment	287,707	268,757	1177	557,641
%	51.6	48.2	0.2	-
Total Minority Enrollment	159,900	135,289	319	295,508
%	55.6	50.3	25.1	53.0
By Race	Female	Male	Unknown	Totals
American Indian/Alaska Native	1,791	1,478	9	3,278
%	0.6	0.5	0.7	0.6
Asian	68,401	54,992	83	123,476
%	23.8	20.5	6.5	22.1
Black/African American	39,822	32,232	63	73,117
%	13.8	12.4	5.0	13.1
Native Hawaiian/Pacific Islander	1,300	1,146	6	2,452
%	0.5	0.4	0.5	0.4
White	114,246	112,368	504	227,118
%	39.7	41.8	39.7	40.7
More Than One Race	10,059	6,554	61	16,674
%	3.5	2.4	4.8	3.0
Unknown/Not Reported	52,088	58,987	544	111,619
%	18.1	21.9	42.8	20.0
By Ethnicity	Female	Male	Unknown	Totals
Not Hispanic	106,220	79,252	609	186,081
%	36.9	29.5	48.0	33.4
Hispanic/Latino	41,500	40,020	129	81,649
%	14.4	14.9	10.2	14.6
Unknown/Not Reported	139,987	149,485	532	290,004
%	48.7	55.6	41.9	52.0

Table 8. NIAAA Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity, FY 2022

	Female	Male	Unknown	Totals
Total Enrollment	1,027	793	3	1,823
%	56.3	43.5	0.2	-
Total Minority Enrollment	704	593	1	1,298
%	68.5	74.8	33.3	71.2
By Race	Female	Male	Unknown	Totals
American Indian/Alaska Native	10.0	3.0	0	13
%	1.0	0.4	0	0.7
Asian	202	174	0	376
%	19.7	21.9	0	20.6
Black/African American	307	322	1	630
%	29.9	40.6	33.3	34.6
Native Hawaiian/Pacific Islander	2	2	0	4
%	0.2	0.3	0	0.2
White	411	247	1	659
%	40.0	31.1	33.3	36.1
More Than One Race	74	38	0	112
%	7.2	4.8	0	6.1
Unknown/Not Reported	21	7	1	29
%	2.0	0.9	33.3	1.6
By Ethnicity	Female	Male	Unknown	Totals
Not Hispanic	866	710	89.5	1,578
%	83.8	83.1	50.0	86.6
Hispanic/Latino	154	73	0	227
%	15.0	9.2	0	12.5
Unknown/Not Reported	7	10	1	18
%	0.7	1.3	33.3	1.0

Table 9. NIAAA Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity, FY 2023

	Female	Male	Unknown	Totals
Total Enrollment	2,018	1,267	9	3,294
%	61.3	38.5	0.3	-
Total Minority Enrollment	1,282	908	3	2,193
%	63.5	71.7	33.3	66.6
By Race	Female	Male	Unknown	Totals
American Indian/Alaska Native	17	6	0	23
%	0.8	0.5	0	0.7
Asian	367	357	1	725
%	18.2	28.2	11.1	22.0
Black/African American	461	363	2	826
%	22.8	28.7	22.2	25.1
Native Hawaiian/Pacific Islander	9	3	0	12
%	0.4	0.2	0	0.4
White	913	438	2	1,353
%	45.2	34.6	22.2	41.1
More Than One Race	176	62	0	238
%	8.7	4.9	0.0	7.2
Unknown/Not Reported	75	38	4	117
%	3.7	3.0	44.4	3.6
By Ethnicity	Female	Male	Unknown	Totals
Not Hispanic	1,600	1,056	5	2,661
%	79.3	83.3	55.6	80.8
Hispanic/Latino	400	179	0	579
%	19.8	14.1	0	17.6
Unknown/Not Reported	18	32	4	54
%	0.9	2.5	44.4	1.6

Table 10. NIAAA Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity, FY 2024

Sex	Female	Male	Unknown	Totals
Total Enrollment	4,888	4,931	15	9,834
%	49.7	50.1	0.2	-
Total Minority Enrollment	3,925	4,425	6	8,356
%	80.3	89.7	40.0	85.0
By Race	Female	Male	Unknown	Totals
American Indian/Alaska Native	25	10	0	35
%	0.5	0.2	0	0.4
Asian	439	643	3	1,139
%	10.1	13.0	20.0	11.6
Black/African American	2,839	3,512	2	6,353
%	58.1	71.2	13.3	64.6
Native Hawaiian/Pacific Islander	11	3	0	14
%	0.2	0.1	0	0.1
White	1,214	625	4	1,843
%	24.8	12.7	26.7	18.7
More Than One Race	211	79	1	291
%	4.3	1.6	6.7	3.0
Unknown/Not Reported	95	59	5	159
%	1.9	1.2	33.3	1.6
By Ethnicity	Female	Male	Unknown	Totals
Not Hispanic	4,331	4,640	8	8,979
%	88.6	94.1	53.3	91.3
Hispanic/Latino	532	254	1	787
%	10.9	5.2	6.7	8.0
Unknown/Not Reported	25	37	6	68
%	0.5	0.8	40.0	0.7