

# Compliance with the NIH Policy on Inclusion Guidelines National Institute on Alcohol Abuse and Alcoholism

## Overview

The mission of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is to generate and disseminate fundamental knowledge about the 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 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.

By supporting a broad range of basic, translational, and clinical research, NIAAA aims to:

- Better understand the health effects of alcohol misuse across the lifespan.
- Reveal the biological and socio-cultural origins of alcohol misuse.
- Remove the stigma associated with alcohol problems.
- Develop evidence-based prevention and treatment strategies that address alcohol misuse across the lifespan.

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 NIH Inclusion Guidelines**

### *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<sup>1</sup> 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 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 in light of 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.

### *Program Monitoring and Grants Management Oversight*

Prior to an award, program officials/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors monitor 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 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 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 plan to increase recruitment reviewed by both the Institute and the pertinent

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<sup>1</sup> See "Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research," [https://grants.nih.gov/grants/peer/guidelines\\_general/Review\\_Human\\_subjects\\_Inclusion.pdf](https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_subjects_Inclusion.pdf)

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.

### *NIAAA Staff Training*

NIAAA program officials and scientific review officers attended the 2020 NIH Inclusion Training for Program Staff and the 2020 NIH Inclusion Training for Review Staff in April 2020. Staff may access the archived training on the NIH staff intranet.

## **NIAAA Aggregate Inclusion Data for FY 2019, FY 2020, and FY 2021: Analysis and Interpretation**

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/gender, race, and ethnicity of the study participants.

NIAAA supported 505, 612, and 666 IERs in fiscal years (FY) 2019, 2020 and 2021, respectively. There was a 21.2% increase in the number of IERs from FY 2019 to FY 2020 and an 8.8% increase in the number of IERs from FY 2020 to FY 2021. These increases were associated with the implementation of changes in the NIH policy regarding IERs.

Tables 2-4 display the enrollment for all NIH-defined clinical research by sex/gender, by race, and by ethnicity for FYs 2019, 2020 and 2021. Tables 5-7 display sex/gender enrollment for NIAAA-supported clinical research by race and ethnicity. Tables 8-10 display data for NIH-defined Phase III clinical trials.

The total enrollment was 256,152 participants in FY 2019, 230,086 participants in FY 2020, and 131,953 participants in FY 2021 (Table 2). The enrollment consisted primarily of IERs with less than 1,000 participants with various sex/gender, race, and ethnicity distributions. In each fiscal year, however, one 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.

In FY 2019 and FY 2020, a very large observational study of veterans with a high proportion of males relative to females (160,415 males: 4,241 females) reported enrollment that primarily fell into the Black/African-American and White race categories, skewing the aggregate data for both sex/gender and race categories. Funding for this study ended in FY 2020. In FY 2021, a

large study using electronic health records from a state in the Pacific Northwest (38,976 females: 27,523 males) reported an enrollment with higher proportions of White and Asian participants relative to other race and ethnicity categories, slightly skewing data for certain race and ethnicity categories. To demonstrate the impact of the two studies on the aggregate percentages, Tables 2-4 include values in parentheses that reflect the percentages after excluding the two large studies.

#### Enrollment by sex

The uneven and fluctuating enrollment of females and males across the reporting period (see Table 2) reflects the disparate male/female enrollment ratios in the two large studies described above. When the two studies are excluded, male/female enrollment numbers are more stable over time (50-55 percent female; see parenthetical percentages shown in Table 2).

#### Enrollment by race

For FY 2021, enrollment data depict a decrease in the number of Black/African American participants and an increase in the number of White participants. These data largely reflect the veteran study described above that ended in FY 2020 and, to a lesser extent, the electronic health record study in FY 2021. When the large studies are excluded, enrollment in race categories is more stable across the reporting period (around 20 percent each year for Black/African American participants and around 62 percent each year for White participants; see parenthetical percentages in Table 3).

FY 2021 data also show an increase in enrollment of Asian participants, driven primarily by the electronic health records study. However, when excluding the large studies, there is still some variability across the reporting period (see parenthetical percentages in Table 3).

The increase in enrollment of Native Hawaiian/Pacific Islander participants in FY 2021 reflects one study that enrolled 865 Native Hawaiian/Pacific Islander participants.

The increase in enrollment of participants with unknown/not reported race in FY 2021 is also driven by the large electronic health record study. After excluding the study, a relative increase in enrollment is still observed, reflecting one study with 1,780 participants of unknown race.

#### Enrollment by ethnicity

Enrollment of Hispanic participants was relatively stable over the reporting period (around 9-10 percent each year). However, because the two large studies included disproportionately more non-Hispanic participants, the percentages increase when the large studies are excluded (around 12-15 percent per year as shown in parenthetical values in Table 4).

#### Phase III Clinical Trials

NIAAA supports very few NIH-defined Phase III clinical trials; therefore, enrollment in these studies represents a small fraction of the total NIAAA enrollment (Tables 8-10). In FY 2019, NIAAA supported seven extramural inclusion enrollment records (IERs); three of them (or 42.9

percent) required valid analyses by sex/gender, race, and ethnicity. In FY 2020 and in FY 2021, NIAAA supported seven IERs and 100% of them required valid analyses by sex/gender, race, and ethnicity. There was fluctuation in the enrollment for sex/gender and certain race categories during the reporting period because different studies reported enrollment in each fiscal year, studies had high enrollment of a specific sex/gender, and/or study sites were located in countries with a high representation of a specific racial group.

### Summary

In summary, noticeable shifts in enrollment for sex/gender and 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](#) (RCDC) areas. NIAAA inclusion data by gender, 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 2019, FY 2020, and FY 2021

**Table 1. Inclusion Data Records for NIH-Defined Extramural and Intramural Clinical Research, FY 2019, FY 2020, and FY 2021**

Fiscal Year	2019	2020	2021
<b>US Site</b>	300	320	314
<b>Non-US Site</b>	25	29	30
<b>Female Only</b>	19	21	23
<b>Male Only</b>	22	19	22
<b>Excluding Male-only &amp; Female-only*</b>	284	309	299
<b>Without Enrollment</b>	180	263	322
<b>With Enrollment</b>	325	349	344
<b>Total</b>	<b>505</b>	<b>612</b>	<b>666</b>

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

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

Sex/Gender	FY 2019	FY 2020	FY 2021
<b>Female</b>	54,361	37,063	73,089
	21.2% (54.8%)	16.1% (50.2%)	55.4% (52.1%)
<b>Male</b>	201,425	192,591	58,646
	78.6% (44.8%)	83.7% (42.6%)	44.4% (47.5%)
<b>Unknown</b>	366	432	218
	0.1% (0.4%)	0.2% (0.7%)	0.2% (0.3%)
<b>Total Enrollment</b>	256,152	230,086	131,953

\*Percentages in parentheses exclude studies with enrollment greater than 50,000 participants (in FY 2019 and FY 2020, one study with 164,656 participants; in FY 2021, one study with 66,499 participants).

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

Race	FY 2019	FY 2020	FY 2021
American Indian/Alaska Native	2,425 0.9% (2.0%)	1,955 0.8% (2.1%)	2,095 1.6% (2.4%)
Asian	6030 2.4% (5.9%)	5,461 2.4% (7.4%)	9,032 6.8% (4.5%)
Black/African American	101,488 39.6% (23.1%)	91,603 39.8% (17.1%)	16,236 12.3% (20%)
Native Hawaiian/Pacific Islander	944 0.4% (0.5%)	753 0.3% (0.4%)	1,655 1.3% (1.6%)
White	131,165 51.2% (62.2%)	115,686 50.3% (63.3%)	88,222 66.9% (61.6%)
More Than One Race	11,288 4.4% (3.2%)	11,794 5.1% (5.3%)	4,484 3.4% (4%)
Unknown/Not Reported	2,812 1.1% (3.1%)	2,834 1.2% (4.3%)	9,959 7.5% (5.9%)
<b>Total Enrollment</b>	<b>256,152</b>	<b>230,086</b>	<b>131,953</b>

\*Percentages in parentheses exclude studies with enrollment greater than 50,000 participants (in FY 2019 and FY 2020, one study with 164,656 participants; in FY 2021, one study with 66,499 participants).

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

Ethnicity	FY 2019	FY 2020	FY 2021
Not Hispanic	229,038 89.4% (83.8%)	208,406 90.6% (85.6%)	114,099 86.5 (84.1)
Hispanic/Latino	26,078 10.2% (15.1%)	20,055 8.7% (11.9%)	13,753 10.4% (15%)
Unknown/Not Reported	1,036 0.4% (1.1%)	1,625 0.7% (2.5%)	4,101 3.1% (0.9%)
<b>Total Enrollment</b>	<b>256,152</b>	<b>230,086</b>	<b>131,953</b>

\*Percentages in parentheses exclude studies with enrollment greater than 50,000 participants (in FY 2019 and FY 2020, one study with 164,656 participants; in FY 2021, one study with data from 66,499 participants).

**Table 5. NIAAA Enrollment for All NIH-Defined Clinical Research,  
Sex/Gender by Race and Ethnicity, FY 2019**

	Sex/Gender	Female	Male	Unknown
	<b>Total Enrollment</b>	54,361	201,425	366
	%	21.8	78.6	0.1
	<b>Minority</b>	26,736	116,667	72
	%	49.2	57.9	19.7
<b>Race</b>	American Indian/Alaska Native	1,014	1,049	2
	%	1.9	0.7	0.5
	Asian	3,249	2,772	9
	%	6.0	1.4	2.5
	Black/African American	14,100	87,373	15
	%	25.9	43.4	4.1
	Native Hawaiian/Pacific Islander	240	704	0
	%	0.4	0.3	0.0
	White	32,482	98,593	90
	%	59.8	48.9	24.6
	More Than One Race	1,887	9,397	4
	%	3.5	4.7	1.1
	Unknown/Not Reported	1,389	1,177	246
	%	2.6	0.6	67.2
<b>Ethnicity</b>	Not Hispanic	46,184	182,771	83
	%	85.0	90.7	22.7
	Hispanic/Latino	7,763	18,266	49
	%	14.3	9.1	13.4
	Unknown/Not Reported	414	388	234
	%	0.80	0.2	63.9



**Table 6. NIAAA Enrollment for All NIH-Defined Clinical Research,  
Sex/Gender by Race and Ethnicity, FY 2020**

	Sex/Gender	Female	Male	Unknown
	<b>Total Enrollment</b>	37,063	192,591	432
	%	16.1	83.7	0.2
	<b>Minority</b>	17,567	110,017	108
	%	47.4	57.1	25.0
<b>Race</b>	American Indian/Alaska Native	798	1,155	2
	%	2.2	0.6	0.5
	Asian	2,777	2,661	23
	%	7.5	1.4	5.3
	Black/African American	8,249	83,338	16
	%	22.3	43.3	3.7
	Native Hawaiian/Pacific Islander	117	636	0
	%	0.3	0.3	0.0
	White	21,500	94,012	174
	%	58.0	48.8	40.3
	More Than One Race	2,197	9,565	32
	%	5.9	5.0	7.4
	Unknown/Not Reported	1,425	1,224	185
	%	3.8	0.6	42.8
<b>Ethnicity</b>	Not Hispanic	32,021	176,204	181
	%	86.4	91.5	41.9
	Hispanic/Latino	4,446	15,559	50
	%	12.0	8.1	11.6
	Unknown/Not Reported	596	828	201
	%	1.6	0.4	46.5

**Table 7. NIAAA Enrollment for All NIH-Defined Clinical Research,  
Sex/Gender by Race and Ethnicity, FY 2021**

	Sex/Gender	Female	Male	Unknown
	<b>Total Enrollment</b>	73,089	58,646	218
	%	55.4	44.4	0.2
	<b>Minority</b>	25,548	19,703	81
	%	35.0	33.6	37.2
<b>Race</b>	American Indian/Alaska Native	1,282	812	1
	%	1.8	1.4	0.5
	Asian	5,690	3,597	15
	%	7.8	6.1	6.9
	Black/African American	8,358	7,856	22
	%	11.4	13.4	10.1
	Native Hawaiian/Pacific Islander	1,212	440	3
	%	1.7	0.8	1.4
	White	48,827	39,292	103
	%	66.8	67.0	47.2
	More Than One Race	2,756	1,713	15
	%	3.8	2.9	6.9
	Unknown/Not Reported	4,964	4,936	59
	%	6.8	8.4	27.1
<b>Ethnicity</b>	Not Hispanic	63,807	50,162	130
	%	87.3	85.5	59.6
	Hispanic/Latino	7,490	6,223	40
	%	10.2	10.6	18.3
	Unknown/Not Reported	1,792	2,261	48
	%	2.5	3.9	22.0

**Table 8. NIAAA Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity, FY 2019**

	Sex/Gender	Female	Male	Unknown
	<b>Total Enrollment</b>	104	8	0
	%	92.9	7.1	0.0
	<b>Minority</b>	104	8	0.0
	%	100	100	0.0
<b>Race</b>	American Indian/Alaska Native	0	0	0
	%	0.0	0.0	0.0
	Asian	0	0	0
	%	0.0	0.0	0.0
	Black/African American	104	8	0
	%	100	100	0.0
	Native Hawaiian/Pacific Islander	0	0	0
	%	0.0	0.0	0.0
	White	0	0	0
	%	0.0	0.0	0.0
	More Than One Race	0	0	0
	%	0.0	0.0	0.0
	Unknown/Not Reported	0	0	0
	%	0.0	0.0	0.0
<b>Ethnicity</b>	Not Hispanic	104	100	0
	%	8	100	0.0
	Hispanic/Latino	0	0	0
	%	0.0	0.0	0.0
	Unknown/Not Reported	0	0	0
	%	0.0	0.0	0.0

**Table 9. NIAAA Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity, FY 2020**

	Sex/Gender	Female	Male	Unknown
	<b>Total Enrollment</b>	142	273	0
	%	34.2	65.8	0.0
	<b>Minority</b>	0	0	0
	%	0.0	0.0	0.0
<b>Race</b>	<b>American Indian/Alaska Native</b>	1	0	0
	%	0.7	0.0	0.0
	<b>Asian</b>	0	0	0
	%	0.0	0.0	0.0
	<b>Black/African American</b>	0	0	0
	%	0.0	0.0	0.0
	<b>Native Hawaiian/Pacific Islander</b>	0	0	0
	%	0.0	0.0	0.0
	<b>White</b>	141	273	0
	%	99.3	100.0	0.0
	<b>More Than One Race</b>	0	0	0
	%	0.0	0.0	0.0
	<b>Unknown/Not Reported</b>	0	0	0
	%	0.0	0.0	0.0
<b>Ethnicity</b>	<b>Not Hispanic</b>	142	272	0
	%	100	99.6	0.0
	<b>Hispanic/Latino</b>	0	1	0
	%	0.0	0.4	0.0
	<b>Unknown/Not Reported</b>	0	0	0
	%	0.0	0.0	0.0

**Table 10. NIAAA Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity, FY 2021**

	Sex/Gender	Female	Male	Unknown
	<b>Total Enrollment</b>	5	49	0
	%	9.3	90.7	0.0
	<b>Minority</b>	5	49	0
	%	100	100	0.0
<b>Race</b>	American Indian/Alaska Native	0	0	0
	%	0.0	0.0	0.0
	Asian	4	15	0
	%	80.0	30.6	0.0
	Black/African American	1	34	0
	%	20.0	69.4	0.0
	Native Hawaiian/Pacific Islander	0	0	0
	%	0.0	0.0	0.0
	White	0	0	0
	%	0.0	0.0	0.0
	More Than One Race	0	0	0
	%	0.0	0.0	0.0
	Unknown/Not Reported	0	0	0
	%	0.0	0.0	0.0
<b>Ethnicity</b>	Not Hispanic	5	49	0
	%	100.0	100.0	0.0
	Hispanic/Latino	0	0	0
	%	0.0	0.0	0.0
	Unknown/Not Reported	0	0	0
	%	0.0	0.0	0.0