

NIAAA Compliance with the NIH Policy on Inclusion Guidelines

Overview

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) supports and conducts research on the impact of alcohol use on human health and well-being. 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 genetics, neuroscience, epidemiology, prevention, and treatment.
- 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.

Through both research within NIAAA, and by funding grants at institutions worldwide, NIAAA aims to:

- Better understand the health risks and benefits of consuming alcohol, as well as why it can cause addiction.
- Reveal the biological and socio-cultural origins of excessive drinking.
- Remove the stigma associated with alcohol problems.
- Develop effective prevention and treatment strategies that address the physical, behavioral, and social risks that result from both excessive drinking, and underage alcohol consumption.

NIAAA-funded discoveries have important implications for improving the health and well-being of all people.

Strategies for Ensuring Compliance with Inclusion Guidelines

NIAAA staff at the review, program and grants management levels is aware of the inclusion requirements and address the inclusion of minorities and women explicitly at each stage of the application process, beginning with NIAAA-sponsored Funding Opportunity Announcements (FOA). Each FOA that involves human subjects advises applicants of the NIH requirement to include women and minorities as research participants, unless inclusion is inappropriate for the health of these groups or for the purpose of the research.

Inclusion is addressed again as researchers respond to FOAs or submit independently initiated proposals that incorporate their plans for inclusion. NIAAA program officials answer questions about the inclusion policy and advise applicants on inclusion issues.

As they prepare for review meetings, NIAAA Scientific Review Officers (SROs) address inclusion. Through the package of review materials that SROs send to reviewers, Initial Review Group (IRG) members are informed of the requirement that NIAAA applications must include women and minorities when scientifically appropriate.

At the beginning of every review meeting, SROs remind the IRG members of the requirement that women and minorities should be appropriately and adequately represented in the proposed research. At the IRG meeting, for each application with human subjects, the IRG chair asks reviewers to determine whether inclusion criteria are met adequately. The SRO records these determinations in the summary statement and uses the NIH IMPAC II coding system to indicate if the inclusion of women, minorities, and children is acceptable, and the type of inclusion (e.g., inclusion of both gender groups, women only, or men only). The IMPAC II system will not allow an award to be made until these codes indicate that inclusion of women and minorities is acceptable.

When an IRG decides that an application's inclusion status is unacceptable, the application receives an administrative bar-to-funding and the applicant must correct the inclusion issue before an award can be made. NIAAA program officials discuss issues of non-compliance with the applicants and advise them on how to resolve the problem(s). The applicant then modifies the project or provides additional information to address reviewer concerns. These procedures ensure that NIAAA funds no applications with unacceptable inclusion of women and minorities.

Between January 2013 and October 2014, NIAAA received 15 applications (0.6%) with unacceptable minority or sex/gender inclusion, out of a total of 2,509 applications. Of 529 awards made during this same period, 226 applications (42.7%) involved human participants, all of which met the inclusion requirements as submitted (see Tables A and B).

For each protocol, investigators are required to provide planned enrollment data and actual annual cumulative enrollment data and describe the sex/gender and race/ethnicity of study participants at the aggregate level. NIAAA program officials help ensure compliance by monitoring recruitment and enrollment of the ongoing studies. Planned and accrued data are recorded and tracked electronically through the NIH Inclusion Management System. Planned enrollment data are submitted with competing applications, and actual cumulative enrollment data are submitted with noncompeting applications and progress reports. In a given year, data are submitted for the previous year.

The inclusion management system allows program officials to stay abreast of the status of inclusion in their portfolios, advising researchers as necessary to keep inclusion on track. The Institute also uses the inclusion management system to prepare the biennial inclusion reports for the National Advisory Council on Alcohol Abuse and Alcoholism in compliance with PL 103-43, Section 492B(2)(f).

- Phase III Clinical Trials

NIAAA pays particular attention to NIH-defined Phase III clinical trials to ensure that each study meets NIH requirements for inclusion of minorities and women. Phase III clinical trial investigators are required to design and conduct their studies such that valid analyses of

differences in intervention effects between sex/gender groups and racial/ethnic groups can be accomplished.

Grants management officers, SROs, and program officials participate together in ensuring that Phase III clinical trials are identified. The designation of each potential Phase III trial is considered by the SRO before review of the application by the IRG takes place. SROs are particularly attentive to these large, expensive projects. These projects' budgets are such that the applications must receive program approval before they are submitted for review. In addition to review procedures, each potential Phase III trial undergoes internal discussion and scrutiny at NIAAA and the decision as to whether it is a Phase III trial is made. Along with reviewers and review staff, the NIAAA staff responsible for data and safety monitoring and the extramural Divisions responsible for Phase III clinical trials pay special attention to these studies, and distinctive coding identifies them in the NIH IMPAC II system. Once these trials are identified, designated staff work with program officials as needed to assist in proper recording and tracking of planned and actual accrual enrollment data.

- Staff Training on the NIH Inclusion Policy and Use of IMPAC II Inclusion Management System

NIAAA extramural scientific staff and grants management officials are encouraged to take NIH Staff Training on Sex/Gender, Race, and Ethnicity Inclusion in Clinical Research Studies which addresses the inclusion policy and implementation as well as NIH staff roles and responsibilities. Inclusion guidelines, course materials and reference documents on population tracking are readily available online. The NIAAA Science Policy Branch offers training and one-on-one demonstrations to assist staff in the proper use of the electronic inclusion tracking system. The Science Policy Branch also regularly monitors enrollment data, disseminates relevant information and works closely with program administrators on an individual basis to ensure that protocols are appropriately tracked and that planned and accrual enrollment data are properly recorded in the system.

NIAAA Aggregate Inclusion Data for the Reporting Period FY 2013-FY 2014

NIAAA supported 315 extramural and intramural research protocols in FY 2013, and 314 extramural and intramural research protocols in FY 2014, that involved human research participants and were required to be monitored for inclusion. The protocols included research conducted at foreign sites. In FY 2013, 199 protocols had enrollment data representing 305,030 human participants, and in FY 2014, 215 protocols had enrollment data representing 310,429 human participants. The total enrollment in FY 2014 was slightly increased compared to the total enrollment at the end of the last reporting period (FY 2012), when 299,627 participants were enrolled in 201 protocols.

- Inclusion Data – Gender

In FY 2013 and FY 2014, the total enrollment of females in NIAAA-supported clinical research (extramural and intramural), including Phase III trials, was 45.2% and 44.3%, respectively, compared to 46% of the total enrollment in both FY 2011 and FY 2012 (Table 1).

For extramural research only, the enrollment of female participants during the reporting period was consistent with the total enrollment for all NIAAA clinical research described above (Tables 2, 3).

NIAAA supports very few Phase III clinical trials; therefore, enrollment in these studies represents a very small proportion of the total NIAAA enrollment. In both FY 2013 and FY 2014, two extramural Phase III trials were ongoing and reported enrollment data. The percentage of female participants enrolled in Phase III clinical trials was 81.1% in FY 2013 and 79.3% in FY 2014 (Tables 4, 5).

For intramural studies, the total female enrollment was 36.8% in FY 2013 and 54.2% in FY 2014 (Tables 6,7). The change from FY 2013 to FY 2014 was due to a substantial increase in total enrollment as a result of a large NIAAA-supported epidemiological study conducted by the intramural program.

- Inclusion Data – Race and Ethnicity

For NIAAA-supported extramural research, the enrollment percentages among the race categories remained relatively consistent in FY 2013 and FY 2014, with the exception of an approximately 2-fold decrease in the Unknown/Not Reported category (Tables 2,3). In the case of ethnicity, the Hispanic category decreased 2.6-fold from FY 2013 to FY 2014 (Tables 2,3). No significant change in enrollment across fiscal years for either race or ethnicity categories was observed for extramural Phase III clinical trials (Tables 4,5). For intramural research, the enrollment percentages among most race and ethnicity groups were consistent from FY 2013 to FY 2014 with the exceptions of the Hawaiian/Pacific Islander category which increased by more than 4-fold, the Unknown/Not Reported category which decreased 3.5 fold, and the Hispanic category which increased almost 4-fold (Tables 6, 7).

**Table A. Level of Compliance with Inclusion Policy in New Extramural Grant
Applications as Assessed During Scientific Peer Review
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM**

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total Number of Applications Reviewed	(#)	364	399	54	417	393	416	106	360
Number of Applications with Human Subjects	(#)	176	187	3	214	205	211	52	182
Number (percent) of Applications approved by IRG as submitted	(#)	174	183	2	212	203	209	52	180
	(%)	98.86%	97.86%	66.67%	99.07%	99.02%	99.05%	100%	98.9%
Number (percent) of Applications with unacceptable <i>minority-only</i> inclusion	(#)	0	0	1	1	0	0	0	1
	(%)	0%	0%	33.33%	0.47%	0%	0%	0%	0.55%
Number (percent) of Applications with unacceptable <i>sex/gender-only</i> inclusion	(#)	0	1	0	0	2	1	0	1
	(%)	0%	0.53%	0%	0%	0.98%	0.47%	0%	0.55%
Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion	(#)	2	3	0	1	0	1	0	0
	(%)	1.14%	1.6%	0%	0.47%	0%	0.47%	0%	0%
Total Number (percent) of Applications with unacceptable minority inclusion	(#)	2	3	1	2	0	1	0	1
	(%)	1.14%	1.6%	33.33%	0.94%	0%	0.47%	0%	0.55%
Total Number (percent) of Applications with unacceptable sex/gender inclusion	(#)	2	4	0	1	2	2	0	1
	(%)	1.14%	2.14%	0%	0.47%	0.98%	0.95%	0%	0.55%
Total Number (percent) of unacceptable Applications as submitted	(#)	2	4	1	2	2	2	0	2
	(%)	1.14%	2.14%	33.33%	0.93%	0.98%	0.95%	0%	1.1%

**Table 1. Subjects Enrolled by Gender Categories
(Extramural and Intramural)**

	FY 2013	FY 2014
Females	137,758	137,392
	45.2%	44.3%
Males	162,029	171,224
	53.1%	55.2%
Unknown	5,243	1,813
	1.7%	0.6%
Total	305,030	310,429
	100.0%	100%

protocols 199 215

Table 2. FY 2013 Aggregate Enrollment Data for All Extramural Research Protocols

Number of Protocols

New Form: Total of All Subjects Reported Using the 1997 OMB Standards With Enrollment Data: 186

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	1,611	4,760	24,164	335	76,896	8,562	19,848	136,176	99,217	26,503	10,456	136,176
	1.18%	3.5%	17.74%	0.25%	56.47%	6.29%	14.58%	45.28%	72.86%	19.46%	7.68%	45.28%
Male	1,645	4,434	37,318	283	94,170	2,304	19,167	159,321	128,825	23,689	6,807	159,321
	1.03%	2.78%	23.42%	0.18%	59.11%	1.45%	12.03%	52.98%	80.86%	14.87%	4.27%	52.98%
Unknown	85	7	74	2	364	10	4,697	5,239	518	4,054	667	5,239
	1.62%	0.13%	1.41%	0.04%	6.95%	0.19%	89.65%	1.74%	9.89%	77.38%	12.73%	1.74%
Total	3,341	9,201	61,556	620	171,430	10,876	43,712	300,736	228,560	54,246	17,930	300,736
	1.11%	3.06%	20.47%	0.21%	57%	3.62%	14.54%	100%	76%	18.04%	5.96%	100%

Table 3. FY 2014 Aggregate Enrollment Data for All Extramural Research Protocols

Number of Protocols
New Form: Total of All Subjects Reported Using the 1997 OMB Standards With Enrollment Data: 199

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	1,194	5,535	20,577	270	67,852	9,882	9,833	115,143	98,486	8,529	8,128	115,143
	1.04%	4.81%	17.87%	0.23%	58.93%	8.58%	8.54%	42.74%	85.53%	7.41%	7.06%	42.74%
Male	1,392	5,256	37,142	459	95,186	2,747	10,247	152,429	136,305	9,893	6,231	152,429
	0.91%	3.45%	24.37%	0.3%	62.45%	1.8%	6.72%	56.58%	89.42%	6.49%	4.09%	56.58%
Unknown	1	19	27	0	131	8	1,623	1,809	189	48	1,572	1,809
	0.06%	1.05%	1.49%	0%	7.24%	0.44%	89.72%	0.67%	10.45%	2.65%	86.9%	0.67%
Total	2,587	10,810	57,746	729	163,169	12,637	21,703	269,381	234,980	18,470	15,931	269,381
	0.96%	4.01%	21.44%	0.27%	60.57%	4.69%	8.06%	100%	87.23%	6.86%	5.91%	100%

Table 4. FY 2013 Aggregate Enrollment Data for Extramural Phase III Research Protocols

Number of Protocols
New Form: Total of All Subjects Reported Using the 1997 OMB Standards With Enrollment Data: 2

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	2	8	399	2	170	60	35	676	625	41	10	676
	0.3%	1.18%	59.02%	0.3%	25.15%	8.88%	5.18%	81.06%	92.46%	6.07%	1.48%	81.06%
Male	1	3	16	0	113	10	15	158	137	20	1	158
	0.63%	1.9%	10.13%	0%	71.52%	6.33%	9.49%	18.94%	86.71%	12.66%	0.63%	18.94%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
								0%				0%
Total	3	11	415	2	283	70	50	834	762	61	11	834
	0.36%	1.32%	49.76%	0.24%	33.93%	8.39%	6%	100%	91.37%	7.31%	1.32%	100%

Table 5. FY 2014 Aggregate Enrollment Data for Extramural Phase III Research Protocols

New Form: Total of All Subjects Reported Using the 1997 OMB Standards **Number of Protocols With Enrollment Data: 2**

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	2	11	469	0	204	83	57	826	767	55	4	826
	0.24%	1.33%	56.78%	0%	24.7%	10.05%	6.9%	79.27%	92.86%	6.66%	0.48%	79.27%
Male	2	5	23	0	145	16	9	200	174	26	0	200
	1%	2.5%	11.5%	0%	72.5%	8%	4.5%	19.19%	87%	13%	0%	19.19%
Unknown	0	0	0	0	0	0	16	16	16	0	0	16
	0%	0%	0%	0%	0%	0%	100%	1.54%	100%	0%	0%	1.54%
Total	4	16	492	0	349	99	82	1,042	957	81	4	1,042
	0.38%	1.54%	47.22%	0%	33.49%	9.5%	7.87%	100%	91.84%	7.77%	0.38%	100%

Table 6. FY 2013 Aggregate Enrollment Data Intramural Research Protocols

New Form: Total of All Subjects Reported Using the 1997 OMB Standards **Number of Protocols With Enrollment Data: 13**

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	6	69	403	3	989	20	92	1,582	1,456	71	55	1,582
	0.38%	4.36%	25.47%	0.19%	62.52%	1.26%	5.82%	36.84%	92.04%	4.49%	3.48%	36.84%
Male	5	96	727	2	1,695	34	149	2,708	2,537	123	48	2,708
	0.18%	3.55%	26.85%	0.07%	62.59%	1.26%	5.5%	63.06%	93.69%	4.54%	1.77%	63.06%
Unknown	0	0	0	0	0	0	4	4	0	0	4	4
	0%	0%	0%	0%	0%	0%	100%	0.09%	0%	0%	100%	0.09%
Total	11	165	1,130	5	2,684	54	245	4,294	3,993	194	107	4,294
	0.26%	3.84%	26.32%	0.12%	62.51%	1.26%	5.71%	100%	92.99%	4.52%	2.49%	100%

Table 7. FY 2014 Aggregate Enrollment Data Intramural Research Protocols

		Number of Protocols											
		New Form: Total of All Subjects Reported Using the 1997 OMB Standards							Enrollment Data 16				
		Total of All Subjects by Race							Total of All Subjects by Ethnicities				
		American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown / Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female		349	936	5,233	108	14,968	353	302	22,249	18,154	4,029	66	22,249
		1.57%	4.21%	23.52%	0.49%	67.27%	1.59%	1.36%	54.2%	81.59%	18.11%	0.3%	54.2%
Male		265	844	4,037	118	12,865	304	362	18,795	15,476	3,229	90	18,795
		1.41%	4.49%	21.48%	0.63%	68.45%	1.62%	1.93%	45.79%	82.34%	17.18%	0.48%	45.79%
Unknown		0	0	0	0	0	0	4	4	0	0	4	4
		0%	0%	0%	0%	0%	0%	100%	0.01%	0%	0%	100%	0.01%
Total		614	1,780	9,270	226	27,833	657	668	41,048	33,630	7,258	160	41,048
		1.5%	4.34%	22.58%	0.55%	67.81%	1.6%	1.63%	100%	81.93%	17.68%	0.39%	100%

