DEPARTMENT OF HEALTH AND HUMAN SERVICES
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2025 TRIENNIAL ADVISORY COUNCIL REPORT CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES
Fiscal Years 2022 - 2024

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NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL
REPORT MONITORING ADHERENCE TO THE NIH POLICY ON THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH AS REPORTED IN FISCAL YEARS 2022 - 2024
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I. BACKGROUND/OVERVIEW

The mission of the National Institute for Dental and Craniofacial Research (NIDCR) is to advance fundamental knowledge about dental, oral, and craniofacial (DOC) health and disease and translate these findings into prevention, early detection, and treatment strategies that improve overall health for all individuals and communities across the lifespan. We accomplish our mission through five strategic priorities:

- *Integrate Oral and General Health*. Advance discoveries across the translational research spectrum and drive innovations that improve the early diagnosis, prevention, and treatment of DOC diseases across the lifespan.
- *Precision Dental Medicine*. Develop more precise and individualized treatments for the management and prevention of DOC diseases.
- *Translate and Implement*. Accelerate the translation of research and the implementation of new discoveries into oral and general healthcare practices that reduce health disparities and improve oral health outcomes for individuals and communities worldwide.
- *Diverse Research Pipeline*. Nurture future generations of DOC researchers and oral health professional scholars who can address public health needs within a continually evolving landscape of science and technology advances.
- *Partner and Collaborate*. Expand existing partnerships and create new ones to advance the NIDCR research enterprise and increase its reach and impact.

NIDCR aspires to transform human lives through scientific discoveries and innovations that advance DOC health and overall wellbeing for all.

The NIH Revitalization Act of 1993 directed the NIH to establish guidelines for inclusion of women and minorities in NIH-funded clinical research. 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 in Clinical Research on November 28, 2017, to require studies that are NIH-defined Phase III clinical trials to report the results of analyses by sex and race and/or ethnicity, and those that are defined as applicable clinical trials must report results to ClinicalTrials.gov. This requirement is in effect 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, addresses consideration of individuals of all ages in NIH-funded

clinical research and requires reporting of participant age at enrollment in annual progress reports. The policy is in effect for all grant applications submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated on or after this date.

The 21st Century Cures Act also amended the frequency from biennial to triennial for reporting inclusion activities to advisory councils and providing the Report of the NIH Director on the Inclusion of Women and Minorities. The triennial report provides information from each NIH Institute and Center (IC) on inclusion of participants in NIH-defined clinical research in fiscal years 2022-2024 (FY22-FY24). This report of monitoring adherence to inclusion policies being presented to the National Advisory Dental and Craniofacial Research Council (NADCRC) presents NIDCR's activities related to fulfilling its responsibilities under these statutes.

II. STRATEGIES FOR ENSURING POLICY COMPLIANCE

The implementation of inclusion guidelines involves the participation of NIH Review, Program, Policy, and Grants Management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidelines when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex, race, ethnicity, and age. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex, 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. Review groups make initial recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. The NADCRC performs the second level of review.

Effective January 2025, the new Simplified Framework for NIH Peer Review Criteria reorganizes peer review criteria into three central Factors: (1) importance of the research (significance, innovation), (2) rigor and feasibility (approach), and (3) expertise and resources (investigator, environment). Inclusion criteria and coding (considerations of sex, inclusion across the lifespan, race/ethnicity of the study population) and plans for valid design and analysis of Phase III clinical trials, previously evaluated under Additional Review Criteria, will be integrated within Factor 2 (rigor and feasibility). This change will help to emphasize the importance of these criteria in evaluating scientific merit.

Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received. If issues are raised in peer review, Program and/or Grants Management staff notify Principal Investigators, who are required to address these issues prior to funding. Prior to NIDCR funding a new award, Program staff are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. For NIH-defined Phase III clinical trials, Program staff review applications for the requirement that sex and race

and/or ethnicity analyses are planned. Grants Management staff ensure that unacceptable inclusion plans in applications are resolved prior to issuing an award. Further, for awards that require inclusion monitoring, Program staff monitor actual enrollment progress in annual and final progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, Program staff monitor annual and final progress reports for the requirement to conduct analyses by sex and race and/or ethnicity. Grants Management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that inclusion information is appropriately documented in the official grant file.

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 renewal, the intramural investigator documents the number, sex, race, and ethnicity of those who were accrued during the past year; any issues with accrual are documented, and a plan to address accrual deficiencies is reviewed by the Institute and the pertinent IRB. Dr. Janice Lee, Clinical Director of the Division of Intramural Research at NIDCR, is responsible for overseeing protocol recruitment efforts of NIDCR intramural investigators and ensuring they make efforts to include appropriate representation of sex, race, and ethnicity in their studies. The NIH Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the NIH Office of Extramural Research and the NIH Office of Research on Women's Health.

The NIH Revitalization Act of 1993 and subsequent statutes have stipulated that NIH staff and extramural investigators understand the requirement of the statutes and their impact on the conduct of clinical research. Dr. Dena Fischer, Director for the Center for Clinical Research in the Division of Extramural Research at NIDCR, has provided guidance to NIDCR's Extramural Program Officials/Directors about the inclusion guidelines. Dr. Fischer is a member of the NIH Inclusion Operating Procedures Workgroup, which reviews the tracking system used by NIH to capture inclusion data and recommends changes as needed. NIDCR Extramural Program Officials/Directors provide assistance to extramural investigators to ensure that target and current enrollment information for the inclusion of human subjects on the basis of sex, race, ethnicity, and age are included in grant applications and provided in progress reports. Further, NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for Program staff. NIDCR Program Officials/Directors, Scientific Review Officers, and Grants Management staff may access the training on the NIH staff intranet.

III. ANALYSIS AND INTERPRETATION OF DATA

All NIDCR Extramural and Intramural Clinical Research Studies

The data summarized in this report comprise cumulative inclusion data for NIDCR-supported extramural and intramural studies that require inclusion monitoring.

In FY22, 23,040 participants were enrolled in 172 NIDCR-supported studies of 334 studies that required inclusion monitoring. In FY23, 35,720 participants were enrolled in 187 of 365 NIDCR-supported studies that required inclusion monitoring, and in FY24, 31,440 participants were enrolled in 205 of 373 NIDCR-supported clinical studies that required inclusion monitoring. The number of Inclusion Enrollment Records (IERs), representing studies requiring inclusion monitoring, steadily increased from FY22 to FY24, as did the number of IERs for which enrollment was reported (Table 1).

Aggregate FY22 data (Table 3) revealed that 54.7% of enrolled participants in all NIDCR-supported extramural and intramural clinical research studies were female, 44.1% were male, and sex was unknown for 1.2%. In FY23, the percentage of enrolled female participants increased to 62.8% while the percentage of male participants decreased (36.2%), and sex was unknown for 1.0%, primarily due to a few female-only studies contributing significantly to female study participant enrollment. In FY24, NIDCR-supported clinical research study participation by sex was similar to FY 2022, with 53.0% female participants, 45.6% male participants, and sex was unknown for 1.4%.

In FY22 through FY24, distribution by race (Table 4A) indicated that Whites had the highest rates of participation (48.4% in FY22, 56.7% in FY23, 48.4% in FY24). Black / African American participation was 21.8% in FY22, 22.3% in FY23, and 30.1% in FY24. In FY22, Asian participation was 5.2%; it was 5.3% in FY23 and 5.6% in FY24. American Indian / Alaska Native participation was 1.1% in FY22, 0.6% in FY23, and 0.6% in FY24. Race was unknown / not reported or refused identification for 17.1% of participants in FY22, 10.1% FY23, and 10.7% in FY24. The racial distribution of research participants remained relatively consistent in FY22 and FY23, with a slight increase in minority enrollment for NIDCR-supported clinical research in FY24. Distribution by ethnicity (Table 4B) indicated that study participants identifying as Hispanic / Latino represented 13.0% of enrolled participants in FY22, 12.4% in FY23, and 12.3% in FY24. Ethnicity was unknown / not reported for 12.8% in FY22, 4.6% in FY23, and 4.8% in FY24. Hispanic / Latino participation remained consistent during the reporting timeframe from FY22 to FY24 and was greater than Hispanic / Latino participation reported for all-NIH clinical research during the same timeframe (NIH-wide Hispanic / Latino participation ranged from 6.9% to 11.9% in FY22 to FY24).

Tables 2, 5, 6A and 6B display the total number of participants enrolled in NIDCR-supported Phase III clinical trials between FY22 and FY24. All NIDCR-supported Phase III clinical trials are required to conduct and report the results of analyses by sex, race and/or ethnicity; further, NIDCR-supported applicable NIH-defined Phase III clinical

trials are required to report these analyses to ClinicalTrials.gov (see NOT-OD-18-014). In FY22, 2698 participants were enrolled in seven Phase III clinical trials; 3975 participants were enrolled in 11 Phase III trials in FY23, and 1578 participants were enrolled in seven Phase III trials in FY24 (Table 2). Phase III trial participation by sex was consistent across the reporting years, with 54.6% of female participants enrolling in Phase III trials in FY22, 51.0% in FY23, and 50.8% in FY24 (Table 5). In FY22, 30.7% of Phase III clinical trial participants were White, and White participation decreased to 26.9% in FY23 and 21.7% in FY24 (Table 6A). In FY22 through FY24, Black / African American Phase III trial participation was similar to that for White participants. Black / African American participants represented 28.4%% of Phase III clinical trial participants in FY22, 22.8% in FY23, and 19.7% in FY24. Race was unknown or not reported by 25.1% of Phase III clinical trial participants in FY22, 35.9% in FY23, and 54.5% in FY24. The high percentage of unknown or not reported race that increased over the reporting timeframe may have affected the relative distribution across the race categories. This trend in race being unknown or not reported was primarily due to three clinical trials with significant enrollment of individuals who self-identified as being of Hispanic or Latino ethnicity, and for whom race was not reported or was reported as unknown. Hispanic / Latino enrollment in Phase III trials was 34.0% in FY22, 33.8% in FY23, and increased to 44.9% in FY24. Across the reporting timeframe from FY22 to FY24, Hispanic / Latino participation in Phase III trials was substantially higher than Hispanic / Latino enrollment for all NIDCR-supported clinical research and was also substantially higher than Hispanic / Latino participation in Phase III trials during the previous reporting timeframe (FY19 to FY22, for which Hispanic / Latino participation ranged from 10-16%). Hispanic / Latino participation in all-NIH Phase III trials ranged from 6.3% to 16.8% over the FY22 – FY24 reporting timeframe. Ethnicity was unknown or not reported by 2.4% of Phase III clinical trial participants in FY22, 14.0% in FY23, and 11.6% in FY24.

Inclusion enrollment data by Research, Condition, and Disease Categorization (RCDC) categories will be on the RCDC Inclusion Statistics Report website (https://report.nih.gov/RISR/) at a later date and are available by request. These data are published annually at this website.

Summary

- The number of NIDCR-supported clinical studies requiring inclusion monitoring increased from FY22 to FY24 (increase from 334 to 373), and the number of cumulative participants enrolled in NIDCR-supported clinical research has trended towards an increase over the reporting timeframe.
- More women than men were enrolled in NIDCR-supported clinical research studies over the reporting timeframe (≥ 53%), with an uptick in FY23 (63%), primarily due to a few female-only studies contributing significantly to female study participant enrollment.
- Study participants identifying as White had higher participation relative to other racial categories from FY22 to FY24. Participation of Blacks / African Americans

increased over the reporting timeframe. Overall, the racial distribution of research participants remained relatively consistent, with a slight increase in minority enrollment for NIDCR-supported clinical research in FY24.

- The number of study participants identifying as Hispanic / Latino remained consistent from FY22 to FY24, while the number of individuals for whom ethnicity was unknown or not reported decreased.
- NIDCR supported between 7 and 11 Phase III clinical trials on a variety of topic areas, including dental caries prevention and treatment, acute post-surgical pain management, oral health promotion, reduction of dental anxiety, and tobacco cessation.
- Phase III clinical trial participation by sex was consistent across the reporting years, with female participation ranging from 51-55%.
- There were similar rates of participation of White and Black / African American Phase III trial participants from FY22 to FY24, and the percentages of participants from these two racial categories decreased over the reporting timeframe. At the same time, there was a high percentage of Phase III trial participants for whom race was unknown or not reported, with an increase from FY22 (25%) to FY24 (55%). This trend in race being unknown or not reported was primarily due to three clinical trials with significant enrollment of individuals who self-identified as being of Hispanic or Latino ethnicity, and for whom race was not reported or was reported as unknown.
- Hispanic / Latino participation in NIDCR-supported Phase III trials was substantial and increased over the reporting timeframe from 34% to 45%.

Conclusions

- The FY22 - FY24 NIDCR inclusion data shows that more women than men were enrolled in NIDCR-supported clinical studies requiring enrollment monitoring. The racial and ethnic distribution of study participants reflects the U.S. population in certain categories, while more work needs to be done to increase enrollment in other categories, such as individuals identifying as American Indian / Alaska Native and Native Hawaiian / Pacific Islander.
- Phase III clinical trial participation in FY22 - FY24 shows that NIDCR-supported Phase III trials have significantly improved the ethnic distribution of trial participants over the reporting timeframe.

TABLES

Table 1: NIDCR Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2022 and 2024

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*
2022	334	162	172	163	9	4	5	163
2023	365	178	187	172	15	9	3	175
2024	373	168	205	189	16	14	4	187

*Inclusion Data Records (IERs) excluding male only and female only include unknown sex, and combination of unknown and any sex.

Table 2: NIDCR Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Clinical Trials and Other Clinical Research Reported Between Fiscal Years 2022 and 2024

	FY 2022		FY 2023		FY 2024	
	Phase III trials*	Other Clinical studies**	Phase III trials*	Other Clinical studies**	Phase III trials*	Other Clinical studies**
Domestic site IERs	7	156	11	161	7	182
Non-US site IERs	0	9	0	15	0	16
IERs excluding male-only and female-only	7	156	10	165	5	182
Female-only IERs	0	4	1	8	1	13
Male-only IERs	0	5	0	3	1	3
Total IERs with enrollment data	7	165	11	176	7	198
Total IERs without enrollment data	19	143	7	171	5	163
Total IERs	26	308	18	347	12	361

* An NIH-Defined Phase III Clinical Trial "usually involves several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments."

** Human subjects studies that are not a NIH-Defined Phase III Clinical Trial

Table 3: NIDCR Enrollment for All NIH-Defined Clinical Research, by Sex

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
2022	23,040	12,595	54.7	10,166	44.1	279	1.2	208	0.9	13	0.1
2023	35,720	22,425	62.8	12,920	36.2	375	1.0	8,642	24.2	3	0.0
2024	31,440	16,668	53.0	14,345	45.6	427	1.4	751	2.4	10	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.

Table 4A: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	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
2022	Female	155	1.2	656	5.2	3,046	24.2	25	0.2	5,351	42.5	823	6.5	2,539	20.2
2022	Male	81	0.8	539	5.3	1,937	19.1	29	0.3	5,751	56.6	586	5.8	1,243	12.2
2022	Unknown	9	3.2	7	2.5	44	15.8	3	1.1	42	15.1	22	7.9	152	54.5
2023	Female	108	0.5	1,062	4.7	4,892	21.8	30	0.1	13,297	59.3	1,113	5.0	1,923	8.6
2023	Male	84	0.7	822	6.4	3,001	23.2	41	0.3	6,914	53.5	591	4.6	1,467	11.4
2023	Unknown	9	2.4	7	1.9	61	16.3	3	0.8	43	11.5	21	5.6	231	61.6
2024	Female	77	0.5	925	5.5	5,858	35.1	28	0.2	7,307	43.8	822	4.9	1,651	9.9
2024	Male	105	0.7	813	5.7	3,570	24.9	49	0.3	7,842	54.7	541	3.8	1,425	9.9
2024	Unknown	10	2.3	7	1.6	31	7.3	3	0.7	54	12.6	22	5.2	300	70.3

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 4B: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity (continued)

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	5,763	45.8	12,595	54.7	8,808	69.9	1,744	13.8	2,043	16.2
2022	Male	3,966	39.0	10,166	44.1	8,124	79.9	1,230	12.1	812	8.0
2022	Unknown	94	33.7	279	1.2	167	59.9	27	9.7	85	30.5
2023	Female	9,239	41.2	22,425	62.8	18,908	84.3	2,746	12.2	771	3.4
2023	Male	5,756	44.6	12,920	36.2	10,580	81.9	1,655	12.8	685	5.3
2023	Unknown	118	31.5	375	1.0	139	37.1	33	8.8	203	54.1
2024	Female	9,320	55.9	16,668	53.0	13,796	82.8	2,229	13.4	643	3.9
2024	Male	6,279	43.8	14,345	45.6	12,144	84.7	1,600	11.2	601	4.2
2024	Unknown	91	21.3	427	1.4	113	26.5	35	8.2	279	65.3

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: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Trials, by Sex

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
2022	2,698	1,474	54.6	1,152	42.7	72	2.7	0	0.0	0	0.0
2023	3,975	2,027	51.0	1,844	46.4	104	2.6	19	0.5	0	0.0
2024	1,578	802	50.8	741	47.0	35	2.2	19	1.2	1	0.1

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

Table 6A: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Trials, Sex by Race and Ethnicity

Fiscal Year	Sex	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
2022	Female	13	0.9	126	8.5	473	32.1	3	0.2	454	30.8	83	5.6	322	21.8
2022	Male	12	1.0	108	9.4	291	25.3	2	0.2	372	32.3	79	6.9	288	25.0
2022	Unknown	0	0.0	0	0.0	3	4.2	0	0.0	2	2.8	1	1.4	66	91.7
2023	Female	12	0.6	167	8.2	510	25.2	4	0.2	545	26.9	93	4.6	696	34.3
2023	Male	16	0.9	168	9.1	395	21.4	3	0.2	522	28.3	105	5.7	635	34.4
2023	Unknown	0	0.0	0	0.0	3	2.9	0	0.0	4	3.8	0	0.0	97	93.3
2024	Female	2	0.2	16	2.0	164	20.4	0	0.0	177	22.1	12	1.5	431	53.7
2024	Male	3	0.4	9	1.2	143	19.3	1	0.1	160	21.6	21	2.8	404	54.5
2024	Unknown	0	0.0	0	0.0	4	11.4	0	0.0	6	17.1	0	0.0	25	71.4

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

Table 6B: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Trials, Sex by Race and Ethnicity (continued)

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	1,104	74.9	1,474	54.6	952	64.6	493	33.4	29	2.0
2022	Male	847	73.5	1,152	42.7	698	60.6	423	36.7	31	2.7
2022	Unknown	6	8.3	72	2.7	65	90.3	2	2.8	5	6.9
2023	Female	1,388	68.5	2,027	51.0	1,088	53.7	703	34.7	236	11.6
2023	Male	1,224	66.4	1,844	46.4	979	53.1	633	34.3	232	12.6
2023	Unknown	12	11.5	104	2.6	6	5.8	9	8.7	89	85.6
2024	Female	542	67.6	802	50.8	358	44.6	364	45.4	80	10.0
2024	Male	490	66.1	741	47.0	319	43.0	331	44.7	91	12.3
2024	Unknown	17	48.6	35	2.2	10	28.6	13	37.1	12	34.3

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