

The National Institute on Deafness and Other Communication Disorders Report: Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019 – FY2021

I. Background/Overview

A. Mission Statement

The National Institute on Deafness and Other Communication Disorders (NIDCD) is one of the institutes and centers that comprise the National Institutes of Health (NIH). The NIH is the federal government's focal point for the support of biomedical research. The NIH's mission is to uncover new knowledge that will lead to better health for everyone. Simply described, the goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability. The NIH is part of the [U.S. Department of Health and Human Services](#).

Established in 1988, the NIDCD is mandated to conduct and support biomedical and behavioral research and research training in the normal and disordered processes of hearing, balance, taste, smell, voice, speech, and language. The institute also conducts and supports research and research training related to disease prevention and health promotion; addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders; and supports efforts to create devices that assist individuals with hearing loss or other communication disorders.

It is estimated that more than 46 million people in the United States have a disorder affecting their hearing, balance, taste, smell, voice, speech, or language. The NIDCD has focused national attention on these areas, with the goal of improving the lives of millions of individuals. The NIDCD has made important contributions to the body of knowledge needed to help those with hearing loss and other communication disorders and to advance research in these areas.

The NIDCD accomplishes its mandate through its [intramural research program](#), which conducts basic and clinical research at the NIH, and through its [extramural research program](#). The NIDCD extramural program supports research grants, career development

awards, individual and institutional research training awards, center grants, and contracts to public and private research institutions and organizations.

B. Institute Portfolio

The NIDCD supports and conducts approximately 1,300 research grants, training awards, and contracts in seven mission areas: hearing, balance, taste, smell, voice, speech, and language. These programs take place within the research laboratories and clinic at the NIH campus in Bethesda, Maryland (intramural research), or in public and private institutions and organizations across the country and around the world (extramural research).

Both intramural and extramural research and training programs include the full spectrum of scientific activities including basic, clinical, and translational research. These studies answer fundamental scientific questions to prevent, screen, diagnose, and treat disorders of human communication.

Our Division of Intramural Research conducts research and offers research training in laboratories and clinics on the NIH campus in Bethesda, Maryland.

Our extramural research program funds research and training opportunities at universities, medical centers, and other institutions throughout the United States and abroad, through research grants, career development awards, and other mechanisms.

II. **Strategies for Ensuring Compliance**

A. Peer Review

- Peer review process and how NIDCD works to resolve inclusion concerns
 - 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 summary statement 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 NIDCD Advisory Council performs the second level of review and makes recommendations for funding to the NIDCD Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NIDCD. 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

- The role of program and grants management in monitoring and oversight of 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 Award, and that this information is appropriately documented in the official grant file.

C. Intramural

- Intramural procedures for monitoring and oversight of inclusion
 - 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 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. NIDCD training approaches

- Institute 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.

III. Analysis and Interpretation of Data

A. Inclusion tables in this report were provided by NIH OER. (See Appendix pp. 7 - 9). The following tables represent NIDCD-only enrollment data for fiscal years (FY) 2019 through 2021. All tables were generated and provided by the central NIH office charged with tracking and reporting inclusion data. Table names and numbers were predetermined centrally.

The following are brief comments and/or clarifications of the NIDCD aggregate inclusion data for each of the tables:

- Table 2-1. Total Inclusion Enrollment Reports (IERs) for NIH-Defined Extramural and Intramural Clinical Research (p. 7).
 - Each IER contains inclusion data for a human subject research component of a project. Therefore, one project may have multiple IERs. "IERs without enrollment" means investigators planned to recruit human subjects but have not enrolled one yet. The NIDCD's total IERs increased from 514 to 610, i.e., 18.68% more, from FY 2019 to FY 2021.

- Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity (p. 8).
 - Inclusion of Minorities should reflect the prevalence of diseases and conditions. Therefore, the appropriate number of minorities varies depending on scientific aims of each project. These aggregate numbers will fluctuate as completed grants no longer report enrollment numbers while new grants are only beginning enrollment.
 - Enrollment data collected in FY 2020 were reported in FY 2021. In 2020, the COVID pandemic affected many clinical studies that halted enrolling subjects according to their grantee institution policy. Therefore, the total cumulative enrollment decreased from 140,285 to 76,197, i.e., 45.68% less, from FY 2020 to FY 2021.
 - Data are based on self-reporting by human subjects. Some subjects do not disclose their race, ethnicity, or sex and/or do not understand the racial and ethnic categories defined by the U.S. Office of Management and Budget, resulting in unknown/not reported data. The proportionally large unknown data is due to one extramural grant project that provided subjects an option not to provide sex/gender, race, and ethnicity data. Because subjects cannot be forced to report their sex/gender, racial, and ethnic data, this practice still meets the NIH policy requirement although it is not ideal for a reporting purpose.

- Table 5-2-2-C. All Enrollment for NIH--Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity (p. 9).
 - An NIH-defined Phase III clinical trial is a broadly-based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or

therapy. Community trials and other population-based intervention trials are also included.

- The extramural program had one Phase III clinical trial, “Efficacy of Tympanostomy Tube for Children with Recurrent Acute Otitis Media” in FY 2019. The original grant application explained that boys are more frequently affected than girls and proposed to reflect that male preponderance in the subject accrual plans. The male-female ratio was appropriate. The black/African American – white ratio reflected the prevalence of otitis media in black lower-socioeconomic-status infants and white lower-socioeconomic-status infants according to the investigator. Because this grant ended, we have no Phase III data for FY 2020 and FY 2021.
 - The intramural had no Phase III trial.
- Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category are available through this link: <https://report.nih.gov/RISR/>.

IV. Summary

NIDCD staff are diligent in the monitoring the enrollment projections and the accrual patterns over the life of the grants. NIDCD staff contact investigators to clarify and/or correct accrual data when necessary.

V. Policy Reference

<https://orwh.od.nih.gov/womens-health-research/clinical-research-trials/nih-inclusion-policies>

Appendix:

Note: The following tables represent NIDCD-only data. All tables were generated and provided by the central NIH office charged with tracking and reporting inclusion data. Table names and numbers were predetermined centrally. Only a subset of tables is contained in this NIDCD report for purposes of clarity.

Table 2-1. Total Inclusion Enrollment Reports (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	514	171	343	315	28	5	5	333
2020	596	204	392	362	30	10	13	369
2021	610	256	354	333	21	13	7	334

*Inclusion Enrollment Reports (IERS) excluding male only and female only include unknown sex/gender, and combination of unknown and any sex/gender(s).

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	% American Indian	Black African	% Black African	Native Hawaiian	% Native Hawaiian	White	% White	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		
						Alaska Native	Alaska Native	Asian	Asian	American	American	Islander	Islander	White	White	Race	Race	Reported	Reported	Hispanic	Hispanic	Latino	Latino	Reported	Reported
2019	Female	22,116	33.8	65,528	48.7	178	0.3	13,347	20.4	3,782	5.8	124	0.2	24,099	36.8	1,224	1.9	22,774	34.8	39,793	60.7	4,047	6.2	21,688	33.1
2019	Male	19,638	33.6	58,513	43.4	154	0.3	13,506	23.1	2,717	4.6	51	0.1	19,259	32.9	1,054	1.8	21,772	37.2	34,572	59.1	2,675	4.6	21,266	36.3
2019	Unknown	118	1.1	10,642	7.9	1	0.0	10	0.1	11	0.1	0	0.0	111	1.0	5	0.0	10,504	98.7	338	3.2	94	0.9	10,210	95.9
2020	Female	23,417	35.5	66,035	47.1	249	0.4	14,724	22.3	3,542	5.4	53	0.1	22,369	33.9	1,230	1.9	23,868	36.1	39,060	59.2	4,328	6.6	22,647	34.3
2020	Male	22,488	35.7	62,939	44.9	295	0.5	15,393	24.5	2,985	4.7	59	0.1	20,246	32.2	1,123	1.8	22,838	36.3	37,145	59.0	3,336	5.3	22,458	35.7
2020	Unknown	86	0.8	11,311	8.1	2	0.0	21	0.2	23	0.2	0	0.0	123	1.1	9	0.1	11,133	98.4	351	3.1	38	0.3	10,922	96.6
2021	Female	20,286	51.2	39,621	52.0	260	0.7	12,311	31.1	4,056	10.2	38	0.1	20,291	51.2	1,230	3.1	1,435	3.6	35,210	88.9	2,971	7.5	1,440	3.6
2021	Male	19,576	55.8	35,084	46.0	331	0.9	12,948	36.9	2,921	8.3	28	0.1	16,594	47.3	961	2.7	1,301	3.7	30,866	88.0	3,023	8.6	1,195	3.4
2021	Unknown	104	7.0	1,492	2.0	26	1.7	15	1.0	23	1.5	1	0.1	158	10.6	16	1.1	1,253	84.0	393	26.3	27	1.8	1,072	71.8

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 5-2-2-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															Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
						American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Hawaiian Pacific Islander	% Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported						
2019	Female	46	51.1	90	36.0	0	0.0	0	0.0	33	36.7	1	1.1	49	54.4	7	7.8	0	0.0	80	88.9	10	11.1	0	0.0
2019	Male	78	48.8	160	64.0	1	0.6	5	3.1	50	31.3	0	0.0	91	56.9	11	6.9	2	1.3	141	88.1	19	11.9	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	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	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	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	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	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	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	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0