Pursuant to the Executive Order entitled “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,” the Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024 has been revised.

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 FY2022 – FY2024

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. The Institute also conducts and supports research and research training in disease prevention and health promotion and the special biomedical and behavioral problems associated with people having communication impairments and disorders.

The NIDCD's extramural grant portfolio demonstrates a balance of basic and clinical research. The intramural research program spans a variety of topics, including, but not limited to, the development, function, and dysfunction of the auditory system, the identification and characterization of genes responsible for hereditary hearing loss, development of gene therapies for hearing loss, and disorders affecting taste and smell function.

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 the inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion. For NIH-defined Phase III clinical trials, 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 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.

- Simplifying review framework
  - Effective January 2025, the new Simplified Framework for NIH Peer Review Criteria reorganizes peer review criteria into three central factors: importance, rigor and feasibility, and expertise and resources. Inclusion criteria and coding 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.

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 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, 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

- NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for program staff. Staff may access the 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. 8 - 10). The following tables represent NIDCD-only enrollment data for fiscal years (FY) 2022 through 2024. 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. 8).
  - 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 620 to 686, i.e., 10.65% more, from FY 2022 to FY 2024.

- Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity (p. 9).
  - 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 2022 were reported in FY 2023. The total cumulative enrollment decreased from 69,840 to 62,922, i.e., 10% less, from FY 2023 to FY 2024 may be affected by two factors. First, some of the short-term studies for emergency COVID-19

responses ended. Second, a non-COVID study that had over 3,500 subjects also ended.

- 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. Furthermore, some investigators provide subjects an option not to disclose sex, race, and ethnicity data. Because subjects cannot be forced to report their sex, 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 by Race and Ethnicity (p. 10).
  - 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 no Phase III clinical trial. The table contains a reporting error. A study had a correct code, i.e., Phase III No, in FY 2023; however, the system automatically changed the Phase III designation in FY 2024. Additional quality assurance processes have been implemented in FY 2025 to minimize future errors.
  - The intramural program had no Phase III clinical trial.

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

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 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	620	249	371	355	16	11	5	355
2023	655	246	409	397	12	12	11	386
2024	686	235	451	439	12	18	15	418

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

Total Enrollment: All NIH-Defined Clinical Research

Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	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	18,783	52.8	35,543	52.2	175	0.5	11,076	31.2	4,542	12.8	38	0.1	16,690	47.0	1,281	3.6	1,741	4.9
2022	Male	17,287	55.8	30,953	45.5	146	0.5	11,389	36.8	3,324	10.7	31	0.1	13,682	44.2	1,026	3.3	1,355	4.4
2022	Unknown	85	5.5	1,546	2.3	4	0.3	25	1.6	27	1.7	0	0.0	146	9.4	12	0.8	1,332	86.2
2023	Female	18,873	51.3	36,778	52.7	227	0.6	10,891	29.6	3,984	10.8	102	0.3	18,469	50.2	1,336	3.6	1,769	4.8
2023	Male	16,700	53.8	31,027	44.4	201	0.6	11,152	35.9	2,522	8.1	24	0.1	14,630	47.2	977	3.1	1,521	4.9
2023	Unknown	107	5.3	2,035	2.9	8	0.4	26	1.3	30	1.5	0	0.0	174	8.6	21	1.0	1,776	87.3
2024	Female	17,092	52.9	32,300	51.3	87	0.3	10,685	33.1	3,109	9.6	51	0.2	15,999	49.5	988	3.1	1,381	4.3
2024	Male	15,922	55.7	28,592	45.4	83	0.3	11,079	38.7	2,328	8.1	46	0.2	13,064	45.7	757	2.6	1,235	4.3
2024	Unknown	139	6.7	2,060	3.3	6	0.3	32	1.6	29	1.4	0	0.0	325	15.8	34	1.7	1,634	79.3

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	18,783	52.8	35,543	52.2	31,343	88.2	2,150	6.0	2,050	5.8
2022	Male	17,287	55.8	30,953	45.5	27,527	88.9	1,777	5.7	1,649	5.3
2022	Unknown	85	5.5	1,546	2.3	396	25.6	24	1.6	1,126	72.8
2023	Female	18,873	51.3	36,778	52.7	31,176	84.8	2,808	7.6	2,794	7.6
2023	Male	16,700	53.8	31,027	44.4	26,161	84.3	2,192	7.1	2,674	8.6
2023	Unknown	107	5.3	2,035	2.9	506	24.9	32	1.6	1,497	73.6
2024	Female	17,092	52.9	32,300	51.3	28,650	88.7	2,592	8.0	1,058	3.3
2024	Male	15,922	55.7	28,592	45.4	25,785	90.2	1,907	6.7	900	3.1
2024	Unknown	139	6.7	2,060	3.3	615	29.9	56	2.7	1,389	67.4

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

All Enrollment: All NIH-Defined Clinical Research

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	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	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
2022	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
2022	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
2023	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
2023	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
2023	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
2024	Female	3	100.0	3	37.5	0	0.0	1	33.3	1	33.3	0	0.0	0	0.0	1	33.3	0	0.0
2024	Male	5	100.0	5	62.5	1	20.0	0	0.0	0	0.0	0	0.0	2	40.0	0	0.0	2	40.0
2024	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

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Female	3	100.0	3	37.5	0	0.0	1	33.3	2	66.7
2024	Male	5	100.0	5	62.5	0	0.0	5	100.0	0	0.0
2024	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0