National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Minutes of Meeting May 28, 2025

Via Videoconference

DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

MINUTES OF THE NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL

May 28, 2025

The 239th meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on May 28, 2025, at 10:01 a.m., via videoconference. The meeting was open to the public from 10:00 a.m. until 1:39 p.m.; it was followed by the closed session for Council business and consideration of grant applications from 2:00 p.m. until adjournment at 3:45 p.m. Dr. Jennifer Webster-Cyriaque presided as Acting Chairperson.

OPEN SESSION

Members Present

- Dr. Terry Dickinson
- Dr. Luisa DiPietro
- Dr. Stephany Duda
- Dr. Paul Krebsbach
- Dr. Jose Moron-Concepcion
- Dr. Jacques Nor
- Dr. Amy Slep

National Institute of Dental and Craniofacial Research

- Dr. Jennifer Webster-Cyriaque, Acting Director
- Dr. Yasaman Shirazi, Executive Secretary, Division of Extramural Activities (DEA)
- Dr. Sanoj Suneja, Acting DEA Director
- Dr. Konstantinia Almpani
- Dr. Hosam Alragiq
- Dr. William Elwood
- Dr. Wendy Knosp
- Dr. Dena Fischer
- Dr. Leah Leinbach
- Dr. Jacqueline Mays
- Dr. Michele McGuirl
- Dr. Paramita Sarkar
- Dr. Kelly Roszko
- Dr. Blake Warner
- Dr. Jamie Kugler
- Dr. Janice Lee
- Dr. Achim Werner

Ms. Julie Orban

Ms. Mable Nee

Ms. Vivian Pham

Mr. Bret Dean

Dr. Lillian Shum

Dr. Amanda Melillo

Dr. Preethi Chander

Dr. Lorena Baccaglini

Dr. Margaret Grisius

Mr. Gabriel Hidalgo-Castro

Guests

Mr. Matthew Miller, Neal R. Gross & Co.

I. WELCOME

Dr. Yasaman Shirazi, Advisory Council Executive Secretary, called the open session of the 239th Advisory Council meeting to order at 10:01 a.m. She noted that members of the public may submit written comments until June 19, 2025, at NIDCRCouncilMail@nider.nih.gov.

II. APPROVAL OF MINUTES FROM PREVIOUS MEETING

Dr. Shirazi asked Advisory Council members if they had corrections or comments regarding the minutes of the September 2024 Advisory Council meeting. There were no comments and the Council voted unanimously to approve the minutes.

Dr. Shirazi noted that the Council's operating procedures were revised and approved at the Closed Advisory Council meeting that took place on April 18, 2025. The operating procedures are available on the National Institute of Dental and Craniofacial Research (NIDCR) website (http://www.nidcr.nih.gov).

III. DIRECTOR'S REPORT AND DISCUSSION

Dr. Webster-Cyriaque began the Director's Report by providing an update on the state of Congress and the National Institutes of Health (NIH) appropriations process. For Fiscal Year 2025 (FY-2025), NIH is operating under a Continuing Resolution that provides funding at the FY-2024 levels through September 30, 2025. The President's budget request for FY-2026 was released in May and outlined major discretionary funding changes, including a funding decrease for NIH of approximately \$18 billion from its FY-2025 enacted levels and the reorganization of NIH. As part of the proposed reorganization, NIDCR would be merged with the National Eye Institute (NEI) and the National Institute of Neurological Disorders and Stroke (NINDS) into a proposed "National Institute on Neuroscience and Brain Research." Congress has begun FY-2026 budget hearings in preparation for developing its own budget to submit to the White House for approval. Dr. Webster-

Cyriaque highlighted the fact that there are four dentists serving in the 119th Congress: Representatives Brian Babin, Paul Gosar, Mike Simpson, and Jeff Van Drew. NIDCR participated in a Congressional Lunch and Learn webinar with congressional staff in January and is scheduled to present at another webinar on June 6 to raise awareness of National Oral Health Month and highlight the importance of oral health and the role of NIDCR in advancing it.

Dr. Webster-Cyriaque reviewed the priorities and vision of the 26th Secretary of the U.S. Department of Health and Human Services (HHS), Robert F. Kennedy, Jr., and the 18th Director of the NIH, Dr. Jay Bhattacharya. Secretary Kennedy's priorities include consolidating HHS mental health and addiction programs; addressing the nation's nutrition by promoting physical activity and health lifestyles; funding cutting-edge research while eliminating risky or non-essential activities; redirecting or eliminating funding related to diversity, equity, and inclusion (DEI); strengthening cybersecurity and health information technology; and restoring public trust in biomedical research. Dr. Bhattacharya's vision includes topics such as improving population health, particularly in relation to chronic diseases; ensuring the generalizability of NIH-funded research; fostering innovation; maintaining the highest ethical standards; prioritizing human-based research technologies; allowing for dissenting perspectives; and restoring public trust in science.

There are several new federal and NIH policies that Dr. Webster-Cyriaque highlighted for the Council. These include a White House Executive Order that pauses research which could make a naturally occurring pathogen or toxin more dangerous to the public, a new NIH policy to improve access to inventions that emerge from intramural research, and an NIH policy update that requires published manuscripts resulting from NIH funding to be submitted to PubMed without embargo. Dr. Webster-Cyriaque also reviewed a series of changes related to NIH grants and awards, including a Notice of Civil Rights Term and Condition of Award that requires grant recipients to comply with new federal antidiscrimination laws, changes to NIH policy on foreign subawards that will prohibit such awards from being nested under the parent grant, updated reporting and disclosure requirements for SBIR/STTR grants that involve a foreign component, new application foreign justification requirements for projects with international collaborators, and updated processes for no-cost extension, which has been temporarily disabled in the electronic Research Administration Commons (eRA Commons) and must now be submitted as prior approval requests to be reviewed and approved by NIH.

Dr. Webster-Cyriaque provided an update on staff changes at NIDCR. Mr. Aaron Condon recently joined the Institute as Deputy Executive Officer and is serving as Acting Executive Officer. Dr. Jay Chiorini has assumed the role of Acting Scientific Director. Dr. Sanoj Suneja is now serving as Acting Director of the Division of Extramural Activities. Dr. Michele McGuirl has been hired as the Chief of the Research Training and Career Development Branch. Dr. Tyrone Spady joins NIDCR as Acting Chief of Staff. Dr. Jeffrey Kroopnick has been named Medical Monitor in the Office of Clinical Trials Operations and Management (OCTOM). Dr. Webster-Cyriaque also announced the retirements of Dr. Lynn King, Dr. Lillian Shum, and Dr. Rena D'Souza, and expressed gratitude for their dedicated service to NIH.

As previously noted, NIDCR's budget remains funded at the FY-2024 enacted level of \$520.2M. In 2024, 78.4% of the budget supported extramural research, while 15.1% was allocated to the NIDCR Intramural Program. Dr. Webster-Cyriaque presented a chart illustrating that while

NIDCR's budget increased between FY-2020 to FY-2023, those increases did not keep pace with inflation, resulting in reduced spending power for the Institute. Over the past 5 years, NIDCR's Research Project Grant (RPG) success rates have matched or exceeded those of NIH overall. NIDCR provides approximately 61% of all NIH dental school funding, which accounted for approximately 41% of NIDCR's extramural budget in FY-2024. Dr. Webster-Cyriaque reviewed examples of NIDCR funded Request for Applications (RFAs) in FY-2024, as well as active RFAs in FY-2025, including several collaborations with other ICs. She also highlighted research concepts recently approved by the Advisory Council that support the Institute's strategic priorities: advancing precision dental medicine, integrating oral and general health, and promoting research translation and implementation. Dr. Webster-Cyriaque provided an overview of NIDCR's clinical trial-related Notices of Funding Opportunities (NOFOs), noting the shift across NIH toward broader, multi-IC umbrella NOFOs, which will result in fewer institute-specific announcements moving forward. NIDCR is also involved in several open NOFOs in NIH's Helping End Addiction Long-term (HEAL) Initiative, as well as those related to translational research and data science.

Dr. Webster-Cyriaque highlighted NIDCR's recently launched Data-Driven Science (DDS) Hub, which is a one-stop shop for data sharing, data management, data generation, and analytic resources. NIDCR has established partnerships with other entities and research programs to share their data, including the BigMouth Dental Data Repository, the Wisconsin Collaborative for Healthcare Quality, and the NIH *All of Us* Research Program, among others. The DDS Hub can be found at ddshub.nih.gov.

NIH recently resumed recruitment for the Intramural Research Training Award (IRTA) Fellowship Program and the National Cancer Institute's (NCI) Cancer Research Training Award (CRTA) scholars after a brief pause. Applicants must be U.S. citizens or permanent residents. Dr. Webster-Cyriaque highlighted several updates to NIH training NOFO requirements, including the parent F and K series NOFOs, which NIDCR will be participating in. She noted that the first due date for the Dual Degree Dentist Scientist Pathway to Independence Award is July 12, 2025. The next due date for the Ruth L. Kirchstein National Research Service Award (NRSA) Institutional Research Training Grant is September 25, 2025. NOFOs with June due dates include: the NIDCR Dentist Scientist Career Transition Award, the NIDCR Small Grant Program for New Investigators, and the Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools. Dr. Webster-Cyriaque also emphasized that all fellowship applications are now subject to the revised review criteria, implemented as part of NIH's broader simplified review initiative. The goal is to ensure consistent identification of the most promising fellowship candidates.

Oral health continues to be a major public health concern nationwide. The cost burden associated with oral health diseases is high and has been a key issue affecting military readiness. Chronic oral diseases are the most prevalent chronic conditions among children and are also common in adults. In addition, chronic oral health diseases can exacerbate other chronic conditions, highlighting their broader impact on overall health. Dr. Webster-Cyriaque noted that tooth decay is the most widespread chronic disease in the U.S., affecting over 90% of the population at some point in their lives. While social factors such as diet, education, and hygiene play a major role in prevention of tooth decay, community water fluoridation offers a prevention tool that operates independently of these factors. Research has demonstrated that the elimination of community water

fluoridation can lead to a twofold increase in dental disease. NIDCR is actively advancing research on fluoride to address questions about its impact and to empower Americans to make informed decisions about fluoride. Dr. Webster-Cyriaque acknowledged the many changes that have taken place at HHS and NIH in recent months but reaffirmed NIDCR's continued commitment to strengthening the nation's dental, oral, and craniofacial (DOC) research enterprise and contributing to transforming the health of the nation.

Discussion

Council members asked clarifying questions about the proposed NIH reorganization and the prohibition of foreign subawards. In response to the White House's reorganization proposal, Dr. Webster-Cyriaque noted that appropriations authority ultimately lies with Congress. Dr. Wendy Knosp, Chief, Science Policy and Planning Branch in the Office of Science Policy & Analysis, said that NIH's congressional justification, which will align with the President's budget request, is under development and will be made publicly available once finalized. The FY-2026 congressional appropriations process will unfold in the coming months through public hearings, which will provide insight on the congressional priorities. No draft appropriation bills have been released at this stage. Dr. Jacques Nor inquired whether the White House provided a rationale for placing DOC research under the proposed neuroscience and brain institute. Dr. Webster-Cyriaque responded that no justification had been provided, though she noted that the proposal aligns with earlier reorganization proposals previously introduced by members of Congress. Dr. Stephany Duda asked whether NIDCR has experienced delays in issuing awards due to the series of new requirements related to grants. Dr. Webster-Cyriaque acknowledged that there have been delays, particularly due to the added layers of review that previously did not exist. NIDCR staff are working diligently to expedite the release of awards. Dr. Amy Slep suggested that it would be helpful for the research community if NIDCR publicly shared information about these additional review requirements on its website. Dr. Terry Dickinson commented on the staffing reduction implications of any proposed decrease in NIDCR's budget. Dr. Webster-Cyriaque noted that the Institute has experienced a staffing reduction of approximately 20%.

IV. HIGHLIGHTING INTRAMURAL RESEARCH AT NIDCR

Dr. Webster-Cyriaque provided an introduction of NIDCR's Division of Intramural Research (DIR) before inviting NIDCR researchers to present recent scientific advances from the Intramural Research Program (IRP). The DIR conducts a broad spectrum of research, ranging from foundational molecular and laboratory research to translational, clinical, and public health studies. This research leverages cutting-edge technologies to address critical questions and discover solutions for unmet dental and medical needs. Currently, NIDCR supports 25 active intramural protocols, roughly evenly split between natural history studies and interventional trials. NIDCR researchers also collaborate on studies managed by other NIH ICs to understand how diseases impact oral health. Among its training programs, NIDCR's Clinical Research Fellowship provides mentored postdoctoral research training opportunities for research-focused dentists on the NIH campus. NIDCR's history in clinical research dates back to the 1970s. Dr. Webster-Cyriaque briefly highlighted several key areas of research emphasis within DIR, including immunology and inflammation; the oral microbiome; pain research and

somatosensation; epithelial and salivary gland biology and dysfunction; skeletal biology; and mechanisms of development and stem cell fate. These research efforts have improved our understanding of wound healing, periodontitis, and DOC disease pathogenesis, while contributing to the development of novel therapeutic strategies and other scientific achievements.

V. PLENARY SESSION 1: SHAPING THE FUTURE OF SALIVARY BIOLOGY: TRANSLATIONAL BREAKTHROUGHS FROM THE NIDCR IRP

Dr. Blake Warner, Stadtman Tenure-Track Investigator and Chief of Salivary Disorders Unit and the Sjögren's Clinical Investigations Team in DIR, provided an overview of NIDCR's mission in salivary gland research program. This research aims to understand disease mechanisms and develop therapeutics for conditions such as xerostomia and Sjögren's syndrome. NIDCR's IRP has nine investigators conducting research on epithelial and salivary gland biology. These investigators conduct research on the basic physiology of secretion to help better understand salivary gland pathology. These efforts have positioned NIDCR's Sjögren's Clinic as a national leader on this condition. The clinic conducts observational, interventional, and basic and translational investigations. Dr. Warner's research focuses on investigating the immunopathology of Sjögren's disease to identify effective therapies in humans.

Dr. Warner presented NIDCR's research on radiation-induced xerostomia that has led to significant translation advances. Acinar cells are particularly susceptible to damage from radiation therapy treatment. Previous research originating with NIDCR researcher Bruce Baum hypothesized that the reengineering of the ductal epithelium would increase fluid permeability and augment function. A long-term series of in vitro and in vivo trials led to the development of adeno-associated virus (AAV) APQ1, which has been shown in human trials to restore parotid saliva flow. However, these initial treatments were dose-limited with short durations of efficacy. Subsequent research at NIH by Dr. Baum and Dr. Chiorini found that an AAV2 vector delivered to the salivary epithelium could restore function long-term in patients with radiation-induced xerostomia. This research in gene therapy has led to the development of therapeutics for the treatment of other conditions, including two FDA-approved hemophilia treatments.

Sjögren's disease (SjD) continues to represent a major unmet medical need in the DOC field. The condition is a chronic, distinct, and systemic autoimmune disease affecting between 2 to 4 million people in the U.S., predominantly women over the age of 40. Notably, individuals with Sjögren's disease are at significantly increased risk for lymphoma. There are no FDA-approved treatments or cures for SjD. To date, clinical trials have failed at Phase I or II, due to three primary barriers: limited understanding of disease pathology, disease heterogeneity, and inadequate trial design and outcome measures. Advances in transcriptomic technologies have deepened the understanding of SjD pathogenesis. Research has identified T and B cell infiltration, upregulation of MHC class I and II, dysregulation of interferons and interferonstimulated genes (ISG), and the regulation of immunoglobulins. These insights have informed recent efforts in RNA sequencing to identify core pathways to be targeted for near-term strategies for treatment. One of the top dysregulated pathways discovered was the JAK-STAT signaling pathway. Using single-cell RNA sequencing, researchers identified target and effector cells, with GZMK+ CD8 T cells being the most expanded cell type and seromucous acinar cells the most

lost cell type. Dr. Warner described how NIDCR researchers used spatial transcriptomics and the Drug2Cell computational pipeline to identify to facitinib as a potential therapeutic agent. Preliminary trials have found that the drug corrected pathogenic inflammation and showed measurable improvements in patients with active disease. This approach represents one of several promising therapeutic approaches being studied by the team at NIDCR.

Vignette: CFTR Corrector Rescues Ductal NOD Mice CFTR Function that Repairs the Gland and the Acinar Cell Function

Dr. Paramita Sarkar, NIDCR Postdoctoral Fellow, presented her research conducted in the laboratory of Dr. Shmuel Muallem on the cystic fibrosis transmembrane conductance regulator (CFTR) protein channel in the context of Sjögren's disease. The CFTR channel is essential for ductal fluid and bicarbonate secretion. Dr. Sarkar's team hypothesized that if CFTR expression is reduced in SjD models, correcting that expression could improve ductal and acinar cell function. Dr. Sarkar discussed how her team developed a non-obese diabetic (NOD) mouse model of SjD. She presented data showing that treatment with CFTR corrector C18 partially restored ductal function and repaired amylase exocytosis by acinar cells.

VI. PLENARY SESSION 2: ADVANCES IN SKELETAL, MATRIX, AND MECHANOBIOLOGY FROM THE NIDCR INTRAMURAL PROGRAM

Dr. Kelly Roszko, Skeletal Disorders and Mineral Homeostasis Section, began her presentation by reviewing the rich history of skeletal tissue and matrix research at NIDCR. The goal of the skeletal disorders and mechanobiology team is "to investigate skeletal tissues comprising the DOC complex to improve diagnosis, prognosis, and treatment of chronic diseases." These tissues include cartilage, bone, teeth, bone marrow, tendons, and ligaments. The group engages in a broad spectrum of collaborative studies, translating research on fundamental cell types and hormones into research on rare diseases, which informs research on more common conditions. As an example of this basic science to rare disease to chronic disease research lifecycle, Dr. Roszko discussed how NIDCR's research on Loeys-Dietz syndrome has informed understanding of temporomandibular disorder (TMD) and related conditions. The focus on rare diseases also leverages the unique strength of the NIH Clinical Center as a national hub for research on rare diseases. The Clinical Center's ability to recruit patients from across the country enables studies with sufficient sample sizes that would otherwise be difficult and cost-prohibitive to conduct regionally.

Dr. Roszko then highlighted two translational programs underway at NIDCR. The first centered on fibrous dysplasia/McCune-Albright syndrome (FD/MAS). NIDCR researcher Dr. Pam Robey discovered that bone marrow skeletal stem cells (SSCs) can produce bone, cartilage, marrow fat, and hematopoiesis-supporting stromal cells. Dr. Robey hypothesized that a mutation of SSCs could be a cause of skeletal diseases, which led to her interest in FD/MAS, a condition with no established treatments. She found that in patients with FD/MAS the gain-of-function mutation prohibited SSCs from making cartilage, marrow adipocytes, or bone marrow stromal cells, and instead only produced abnormal osteoblasts, which are the cause of FD/MAS. This research was translated to the clinic through an ongoing FD/MAS natural history study that is managed by NIDCR and has been active since 1998. Dr. Roszko described how Dr. Amanda Boyce identified

osteoclasts as a treatment target for FD. The RANKL protein plays a central role in osteoclast differentiation and has been found to be highly expressed in FD. Dr. Boyce hypothesized that inhibiting RANKL using monoclonal antibody denosumab could result in decreased lesion activity and increased lesional mineralization by inhibiting osteoclast precursors from differentiating into active osteoclasts. Results of a mouse model study found evidence to support the RANKL inhibition ability of denosumab and resulting in increased bone mineralization. This preclinical work was subsequently translated into a human clinical trial that showed improved physical function and decreased pain in patients treated with denosumab. The Robey lab also continues to explore the potential of SSCs in developing therapies for osteoporosis, osteoarthritis, and aging-related conditions. As part of this effort, the lab is developing adult induced pluripotent stem cells to be used as a human-based research platform in lieu of animal models.

Dr. Roszko then discussed her work on hyperphosphatemic familial tumoral calcinosis (HFTC), a FGF23 deficiency disorder that results in large, debilitating calcifications. Advances in HFTC research have the potential to impact more common chronic diseases, such as renal disease and vascular calcification. Dr. Roszko's team is currently conducting an Investigational New Drug (IND) clinical trial to repurpose an existing medication for HFTC treatment. NIDCR's HFTC research also includes a long-term natural history study and other research projects to define the disease course, establish standard of care, identify predictors of severity, and develop hypotheses from patient observations. Dr. Roszko also described her research on characterizing vascular calcification and identifying biomarkers using 18F–NaF PET/CT imaging. This technique enables the early detection of vascular microcalcification, revealing indicators of disease progression. These insights could help identify high-risk patients and offer a promising biomarker and research endpoint for future studies.

Vignette: Prediction of Craniofacial Growth

Dr. Konstantinia Almpani presented research from the laboratory of Dr. Janice Lee, NIDCR Clinical Director and Chief of the Craniofacial Anomalies and Regeneration Section. Over one-third of all birth defects in the U.S. involve craniofacial differences, which can appear as isolated deformities or as part of a syndromic condition. Skeletal malocclusion is an example of a common craniofacial defect involving abnormal maxillary or mandibular development and can lead to impaired function and other health issues in addition to psychosocial aesthetic concerns. Dr. Almpani discussed her team's research on the role of the cranial base in the development of the maxilla and mandible and skeletal malocclusion through the use of 3D imaging computational prediction models. The validation of these models will enable early and accurate customized treatment plans for individuals with skeletal malocclusions.

VII. PLENARY SESSION 3: UNLOCKING HIDDEN DISEASES: A GENOTYPE-FIRST JOURNEY POWERED BY NIH-NIDCR COLLABORATION

Dr. Achim Werner, Senior Investigator, Stem Cell Biochemistry Section, presented another research example that underscores the close integration of basic and clinical research of NIDCR's IRP. Dr. Werner's laboratory focuses on how cell fate decisions are determined during development, with a particular emphasis on the role of the ubiquitin protein and the ubiquitylation post-translational modification process which controls developmental cell fate decisions. It has been

shown that aberrant ubiquitylation is linked to many diseases, including cancers, autoinflammatory diseases, neurodegeneration, as well as congenital developmental diseases. Dr. Werner described the ubiquitylation catalysis process, which can notably be reversed by deubiquitylase enzymes. His lab uses a collaborative, integrated, genotype-first approach to conduct biochemical and proteomic analyses of patients with undiagnosed diseases to categorize these disease mechanisms and identify potential avenues for treatment. Dr. Werner's lab has three independent research areas, each exploring how particular classes of ubiquitylation enzymes control substrate fate to determine cell fate decisions in health and disease. Research on the UBA1 enzyme has found that mutations of this enzyme can lead to a severe, late-onset autoinflammatory disorder called VEXAS. Studying these mutations has uncovered principles of how regulation of ubiquitin activation controls hematopoietic cell fate decisions.

Dr. Werner presented an overview of the research that led to the discovery and characterization of VEXAS, which is often fatal and has been proven to be more prevalent than previously thought, particularly in males over the age of 50. He described subsequent work in the NIDCR Intramural Program to reveal protein isoforms associated with disease severity and mortality, which can be used to identify patients to be recommended for allogeneic hematopoietic cell transplant. Dr. Werner also presented highlights from NIDCR studies on VEXAS pathogenesis, non-canonical VEXAS mutations, and the use of STING inhibitors to reverse VEXAS myeloid cell inflammation.

Vignette: Experimental Treatment of Chronic Graft-Versus-Host Disease (cGVHD) in an NIH VEXAS Patient

Dr. Jacqueline Mays, Lasker Clinical Research Scholar, Oral Immunobiology, presented on her team's translational advances to improve the health of transplant patients. Dr. Mays' team works with the NIH Clinical Center's hematopoietic cell transplant program to monitor and treat changes in the oral cavity. Hematopoietic cell transplants are curative for several cancers and bone marrow failure syndromes, such as VEXAS syndrome; however, the use of hematopoietic cell transplant is limited due to high rates of cGVHD in transplant patients. Dr. Mays presented on a novel treatment of cGVHD in the oral cavity through photobiomodulation treatment, which is currently being studied in a multi-center Phase II randomized clinical trial called the LIGHT trial. A VEXAS patient enrolled in the trial saw complete resolution of their cGVHD by day 56 of treatment.

VIII. PLENARY SESSION 4: DENTAL PUBLIC HEALTH AT NIDCR

Dr. Hosam Alraqiq, Program Director of the NIDCR Dental Public Health Research Fellowship, presented a historical overview of dental public health research at NIDCR, dating back to the Institute's founding director, Dr. Trendley Dean. Dr. Dean led the first large-scale study on fluoride's effectiveness in preventing tooth decay. In its early years, the Institute, then known as the National Institute of Dental Research (NIDR), also conducted pioneering studies on the severity and prevalence of periodontal disease and, in 1956, developed the Periodontal Index, a vital tool that advanced research in the field. In 1971, with support from Congress, the NIDR

launched the National Caries Program, a comprehensive initiative to address tooth decay. During the 1970s, the Institute also demonstrated the efficacy of fluoride mouth rinses and promoted the expansion of school-based rinse programs nationwide. Studies in the 1980s showed marked improvement in caries prevention in children compared to the previous decade. Over the decades, NIDCR has continued to play a key role in advancing global oral health research and training, in partnership with organizations, such as the International Association for Dental Research and other HHS entities. The Institute has also been deeply involved in the development of the two *Surgeon General's Reports on Oral Health in America*, published in 2000 and 2021. These landmark reports underscored the connection between oral and overall health, detailed improvements in national oral health outcomes, described significant scientific and technological advances, and highlighted ongoing and emerging disparities.

The NIDCR Dental Public Health Research Fellowship began in 1980 and includes a one-year residency and two years of research fellowship. In recent years, the program scope has increased to broaden collaboration opportunities across NIH. Since its inception, the fellowship has graduated 60 dental public health professionals—about half of whom have gone on to public service careers, with others entering academia, the private sector, or pursuing further education. Dr. Alraqiq highlighted notable studies by current and past fellows, including interdisciplinary collaborations on topics such as the oral microbiome, oral cancer screening, bruxism and sleep apnea, and other topics.

Vignette: Snapshots of Fellow Research Experiences

Dr. Leah Leinbach, a third-year Dental Public Health Research Fellow, presented to the Council on her research experiences at NIDCR. Drawing on her background as a hospital-based dentist, Dr. Leinbach explored topics rooted in clinical relevance and patient care. One of her studies analyzed changes in the pharmacologic management of dental problems in U.S. emergency departments during the COVID-19 pandemic, revealing a decline in opioid prescriptions for non-traumatic dental conditions. She also investigated the oral health burden among patients with a history of hematopoietic cell transplantation, focusing on both the clinical and patient-reported characteristics at the time of oral chronic graft-versus-host disease (cGVHD) diagnosis.

IX. CONCEPT CLEARANCES

Dr. Shirazi noted that NIDCR is required to present early-stage research concepts to the Council in a public forum to outline their purpose, scope, and objectives. This process ensures transparency and provides an opportunity for Council review, discussion, and approval, as well as public comment. Approved concepts are subsequently published on the NIDCR website under <u>future research initiatives</u>. NIDCR staff presented three concepts approved by Institute leadership for Council clearance, and designated Council members led the discussions, as summarized below.

Before the concepts presentations, Dr. Michelle McGuirl, Chief of the Research Training and Career Development Branch, provided an update on recent changes to the concept clearance

and NOFO development process. Most notably, NIDCR will now prepare a brief description—referred to as a "forecast"—for each concept submitted to NIH leadership for approval prior to Council presentation. Upon approval, these forecasts will be published on <u>Grants.gov</u>. Dr. McGuirl also noted that members of the public can subscribe to receive alerts about newly posted forecasts through the Grants.gov platform.

Reissuance: Institutional Training for the Predoctoral and Postdoctoral Research Workforce (T90/R90) Award Program

Dr. McGuirl presented a reissue concept for a program formerly known as the Institutional Training for a Dental, Oral, and Craniofacial Research Workforce. In response to the NIH directive to reduce the number of NOFOs, NIDCR has redesigned and broadened the program to serve as a parent award mechanism for other Institutes, Centers, and Offices (ICOs). Dr. McGuirl noted that NIDCR currently issues more T90 awards than any other NIH ICO. To transition the award into a parent mechanism, the program description was revised to remove references to specific research topic areas, making it more flexible for broader NIH participation. Current NIDCR grantees will be able to apply under the reissued program as renewals, rather than submitting new applications. Given its new multi-IC status, Dr. McGuirl anticipates that the NOFO will be issued on an annual basis without interruption. She emphasized the importance of the T90/R90 program in supporting NIDCR's mission to foster a pipeline of independent DOC researchers.

The Council's lead discussants for the concept were Dr. Paul Krebsbach and Dr. Luisa DiPietro. Dr. Krebsbach described the reissue as a timely and strategically sound initiative that supports both NIDCR and NIH priorities. He expressed support for the concept and recommended including more detail in the final NOFO regarding review criteria, expectations for mentoring outcomes, and training metrics. Dr. DiPietro concurred and encouraged NIDCR to continue integrating the recommendations from the Council's Research Workforce Working Group—particularly those focused on tracking long-term career outcomes of trainees, including those who pursue careers outside of research.

The Council unanimously approved the concept, with Dr. Nor recused.

Reissuance: Advancing Research Careers through Mentoring Networks (ARCMN) (UE5) Program

Dr. McGuirl introduced a reissue concept for the program formerly known as the NIDCR Mentoring Network to Promote a Diverse DOC Research Workforce. Similar to the T90/R90 program discussed above, this initiative has been redesigned to function as a trans-NIH parent award mechanism and to align with broader NIH priorities. The purpose of the program is to facilitate structured mentoring relationships between experienced investigators (mentors) and selected participants (mentees) to enhance mentees' grant-writing skills, professional development, and long-term success in pursuing research careers across the biomedical, clinical, behavioral, and social sciences. Eligible mentees include early-career faculty, postdocs, clinician scientists, or graduate students. The UE5 program has been a successful component of NIDCR's

efforts, and the Institute remains committed to supporting early-career faculty and late-stage trainees.

The Council's lead discussants were Dr. Jacques Nor and Dr. Amy Slep. Dr. Nor described the concept as timely and impactful, addressing a critical gap in structured mentoring opportunities for early-career researchers. He cited the MIND the Future program as an example of a highly successful UE5-supported initiative and offered his strong and unconditional support for the reissue. Dr. Slep concurred, emphasizing that the DOC research workforce is at a critical moment nationally, and that this concept is vital to ensuring the health of the DOC research workforce.

The Council unanimously approved the concept.

Advancement of Causal Hypotheses for Human Behaviors that Affect Dental, Oral, Craniofacial, and Oral-Systemic Health Outcomes

Dr. William Elwood, Chief of the Behavioral and Social Sciences Branch, presented a concept focused on advancing research into the causal factors underlying human behaviors that impact DOC health outcomes. He emphasized that this concept aligns closely with NIDCR's strategic plan, which highlights the importance of behavioral components in DOC and oral-systemic health. The initiative seeks to accelerate research aimed at optimizing behaviors that promote wellness, improve DOC care delivery, and prevent disease.

The Council's lead discussants were Dr. Stephany Duda and Dr. Terry Dickinson. Dr. Duda commended the concept for its strong alignment with the NIDCR strategic plan and its potential to enhance clinical decision-making, improve understanding of DOC pain, optimize care, and support the development of cost-effective interventions. She noted the broad scope of the concept and recommended that any resulting NOFOs from this concept be carefully tailored with specificity. Dr. Dickinson also expressed his support for the concept, noting its value in addressing often-overlooked aspects of the practice of dentistry.

The Council unanimously approved the concept.

X. TRIENNIAL CLINICAL RESEARCH REPORT

Dr. Dena Fischer summarized the 2025 triennial report to the Advisory Council on NIDCR's compliance with NIH clinical research guidelines regarding the inclusion of women, minorities, and participants of all ages, and related reporting requirements, as outlined in the 1993 NIH Revitalization Act of 1993 and the 21st Century Cures Act of 2016. Dr. Fischer presented data from 2021-2024, highlighting an overall upward trend in participant enrollment, including an increase in minority participation in FY-2024. Across the reporting period, NIDCR-supported studies enrolled more women than men. While racial and ethnic enrollment rates remained relatively stable, the Institute observed a notable increase in Hispanic/Latino participation in Phase III clinical trials.

CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 1009(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. §§ 1001-1014).

XI. REVIEW OF APPLICATIONS

NADCRC reviewed 443 Research and Training Grant applications requesting Total Project Costs (All Years) at \$985,900,138 and Direct Costs (All Years) at \$636,591,785. The Council recommended 252 Research and Training Grant applications requesting Total Project Costs (All Years) at \$563,364,149 and Direct Costs (All Years) at \$364,662,563.

XII. ADJOURNMENT-3:45 PM

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.

/s/ Jennifer Webster-Cyriaque /s/ Yasaman Shirazi

Dr. Jennifer Webster-Cyriaque Dr. Yasaman Shirazi
Acting Chairperson Executive Secretary
National Advisory Dental and
Craniofacial Research Council Craniofacial Research Council