National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Minutes of Meeting
September 9, 2021

Via Videoconference

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

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NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

MINUTES OF THE
NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL

September 9, 2021

The 228th meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on September 9, 2021, at 9:00 a.m., via video teleconference. The meeting was open to the public from 9:00 a.m. until 2:23 p.m.; it was followed by the closed session for Council business and consideration of grant applications from 2:45 p.m. until adjournment at 3:35 p.m. Dr. Rena D'Souza presided as Chair.

OPEN SESSION

Members Present

Dr. Kathryn Marie Albers
Dr. Joel Collier
Dr. David J. Couper
Dr. Frank Ebetino
Dr. Raul I. Garcia
Dr. Lee A. Niswander
Dr. Jacques Nor, *ad hoc member*
Dr. Wenyuan Shi
Dr. Amy Smith Slep, *ad hoc member*
Dr. Clark M. Stanford
Dr. Joel Strom
Dr. Axel Visel

National Institute of Dental and Craniofacial Research

Dr. Rena D'Souza, Director
Dr. Jonathan Horsford, Office of the Director (OD), Acting Deputy Director
Dr. Alicia Dombroski, Executive Secretary, and Director, Division of Extramural Activities (DEA)
Dr. Matthew P. Hoffman, Scientific Director, Division of Intramural Research (DIR)
Dr. Janice S. Lee, Clinical Director, DIR
Mr. John Prue, OD, Director, Office of Information Technology (OIT)
Dr. Lillian Shum, Director, Division of Extramural Research (DER)
Ms. Kathleen Stephan, OD, Associate Director for Management/Executive Officer
Dr. Denise Stredrick, OD, Acting Director, Office of Science Policy and Analysis (OSPA)
Mr. Jeff Ventura, OD, Director, Office of Communications & Health Education (OCHE)
Ms. Tamera Addison, OD, Office of Administrative Management (OAM)

Ms. Alexandria Alfarano, DER, Center for Clinical Research (CCR)
Mr. Hosam Alraqiq, OD, OSPA
Dr. Lorena Baccaglini, DER, CCR
Dr. Nisan Bhattacharya, DEA, Scientific Review Branch (SRB)
Mr. Brian Brito, OD, OIT
Dr. Preethi Chander, DER, Integrative Biology and Infectious Diseases Branch (IBIDB)
Ms. Tiffany Chen, OD, OCHE
Dr. Zhong Chen, DER, IBIDB
Mr. Starsky Cheng, OD, OIT
Ms. Jennifer Chi, OD, Office of Clinical Trials Operations and Management (OCTOM)
Ms. Alicia Chou, DER, Translational Genomics Research Branch (TGRB)
Mr. Kevin Chu, OD, OIT
Dr. Lois Cohen, OD
Ms. Vickie Contie, OD, OCHE, SCDOB
Ms. Michelle Cortes, DER, IBIDB
Ms. Mary Daum, OD, OCHE
Mr. Bret Dean, OD, OAM
Ms. Sharie Diggs, OD, OAM
Mr. Jimmy Do, OD, FMB
Dr. Bryce Dye, OD, OSPA
Dr. Olga Epifano, DEA, OD
Dr. Dena Fischer, DER, CCR
Dr. Leslie Frieden, DEA, Research Training and Career Development Branch (RTCDB)
Dr. Melissa Ghim, DER, IBIDB
Ms. Angelica Gomez, OD, OAM
Dr. Margaret Grisius, DER, CCR
Mr. Joel Guzman, DER
Dr. Sue Hamann, OD, OSPA
Dr. Marika Heinicke, OD, OCTOM
Ms. Jeannine Helm, DER
Mr. Gabriel Hidalgo, DEA, GMB
Dr. Hiroko Iida, DER, Director, CCR
Dr. Leila Khaki, DER, Behavioral and Social Sciences Research Branch (BSSRB)
Dr. Emir Khatipov, DER, TGRB
Dr. Jimok Kim, DEA, SRB
Dr. Lynn King, DEA, RTCDB
Ms. Robin Latham, OD, OCHE
Dr. Orlando Lopez, DER, IBIDB
Ms. Amber Lowery, OD, OMB
Dr. Nadya Lumelsky, DER, IBIDB
Ms. Jayne Lura-Brown, DER
Ms. Susan Macharia, DEA
Mr. Mike Martin, OD, OAM
Dr. Kevin McBryde, DER
Dr. Tamara McNealy, DER, IBIDB
Ms. Susan Medve, DEA, GMB

Dr. Yun Mei, DEA, SRB
Dr. Amanda Melillo, DER, IBIDB
Ms. Phalla Messina, OD, FMB
Ms. Amy Mhatre-Owens, OD, OCTOM
Mr. Ricky Moore, DEA, SRB
Ms. Mable Nee, OD, FMB
Mr. Paul Newgen, DEA, GMB
Ms. Anna Nicholson, OD, OCTOM
Ms. Linda Orgain, OD, OCHE
Ms. Lisa Peng, OD, OIT
Ms. Debbie Pettitt, DEA, GMB
Dr. Elise Rice, DER, BSSRB
Dr. Melissa Riddle, DER, BSSRB
Ms. Diana Rutberg, DEA, GMB
Dr. Yasaman Shirazi, DEA, SRB
Ms. Angela Simpson, OD, OAM
Dr. Ashley Smith, OD, OIT
Dr. Katie Stein, DER, TGRB
Dr. Shoba Thirumangalathu, DEA, RTCDB
Dr. Jessica Walrath, OD, OSPA
Dr. Jason Wan, DER, IBIDB
Dr. Lu Wang, DER, Chief, TGRB
Dr. Jim Winkler, OD

National Institutes of Health

Dr. Thomas Boddie, Office of the Director, Office of Science Policy
Ms. Joy Jackson Farrar, Events Management Branch
Mr. Lamar Smith, Office of the Director
Dr. Lawrence Tabak, Principal Deputy Director

Guests

Mr. Matthew Miller, Neal R. Gross & Co.
Dr. Tara Schwetz, Associate Deputy Director, Office of the Director; Assistant Director for Biomedical Science Initiatives, White House Office of Science and Technology Policy
Dr. David Yule, University of Rochester Medical Center

I. WELCOME AND INTRODUCTIONS

Dr. Rena D'Souza, Director, NIDCR, called to order the open session of the 228th Advisory Council meeting at 9:07 a.m. Dr. D'Souza began the meeting by highlighting the impressive work of NIDCR staff, Council members, and the community at large during these trying virtual times. She looks forward to a return to an in-person environment, but the Council will likely remain virtual at least until the May 2022 Council meeting. Dr. D'Souza announced that this will be Dr. Alicia Dombroski's last meeting as Executive Secretary to the Advisory Council. Dr. Dombroski's service

will be more fully acknowledged at the January 2022 Council meeting. Drs. Albers, Couper, Stanford, and Strom have agreed to extend their term through this meeting in order to provide the Institute more time to onboard new members. Two of the new members, Drs. Jacques Nor and Amy Smith Slep, who Dr. D'Souza introduced to the Council, will be sitting in as ad hoc members. Dr. Alicia Dombroski, Executive Secretary to the Advisory Council, noted that the Council would be accepting questions and comments from the public via email (NIDCRcouncilmail@nidcr.nih.gov) through September 24th.

II. APPROVAL OF MINUTES FROM PREVIOUS MEETING

Dr. Dombroski asked Council members if there were corrections or comments to be made for the minutes of the May 26, 2021, Advisory Council meeting. There were no comments and the Advisory Council voted unanimously to approve the minutes.

III. REPORT OF THE DIRECTOR, NIDCR

Dr. D'Souza's written January 2021 Director's Report to the Council was provided to the Council members and is available on the NIDCR website (http://www.nidcr.nih.gov). Dr. D'Souza opened her remarks by providing a brief overview of the agenda, which will include a presentation on a new NIH component and a total of 11 concepts for Advisory Council consideration.

NIDCR Staff Updates

Dr. D'Souza announced that Dr. Myung Hee Park has retired as chief of the Molecular and Cellular Biochemistry Section in the Division of Intramural Research. Dr. Park first joined NIDCR as a visiting fellow in 1979 and has been chief of the Molecular and Cellular Biochemistry Section since 1998. Dr. D'Souza briefly discussed her research focus areas and scientific achievements, such as the cellular role of polyamines, and noted that Dr. Park served as president of both the NIH Korean Scientists Association and the NIH chapter of Korean-American Women in Science and Engineering.

Dr. D'Souza also announced that Dr. Akintunde Emiola has joined NIDCR as an Earl Stadtman Investigator and chief of the Microbial Therapeutics Unit, Division of Intramural Research. Dr. Emiola's research utilizes bioinformatic, genomic, and molecular biology tools to study the microbiome in order to discover new therapeutic agents and identify microbial signatures for early detection of disease.

Dr. D'Souza then discussed recent activities of the International Association for Dental Research (IADR) and the American Association for Dental, Oral, and Craniofacial Research (AADOCR). She noted that the latter recently changed its name from the American Association of Dental Research. NIDCR leadership, staff, investigators, and trainees were among the presenters and honorees at the 2021 virtual meeting of the IADR, AADOCR, and the Canadian Association for Dental Research. Dr. D'Souza delivered a presentation on NIDCR programs at the meeting. Dr.

Marie Bernard, NIH Chief Officer for Scientific Workforce Diversity, also delivered a very well-received talk on NIH efforts to improve diversity in the biomedical research workforce. Dr. D'Souza was also pleased to announce that NIDCR's Dr. Lois Cohen received the 2021 IADR Distinguished Scientist Award in Global Oral Health Research for her contributions to social and behavioral research in dentistry. Additionally, Drs. Rei Sekiguchi and Ken Yamada won the Journal of Dental Research's Cover of the Year Award for their paper "Single-Cell RNA-seq Identifies Cell Diversity in Embryonic Salivary Glands." Former NIDCR Director Dr. Martha Somerman received the Jack Hein Public Service Award for her career service promoting oral health research. Dr. Joshua Emrick won the Hatton Competition and predoctoral fellow Jeremie Oliver, a member of Dr. D'Souza's lab, received the Craniofacial Biology Group Award (Junior Category) for his presentation at the meeting.

COVID-19 Update

NIH recently launched a consortium called Researching COVID to Enhance Recovery, or RECOVER, to study the post-acute sequelae of SARS-CoV-2 infection, including what is known as "long COVID." The initiative has begun the planning and implementation grant phase and NIH is currently reviewing applications for the development of data repositories and mobile health platforms. Dr. D'Souza briefly reviewed the NIDCR extramural program's COVID-related work, much of which has been geared toward diagnostics. Dr. D'Souza expressed excitement about the translatability of these tools, COVID research in general, and related digital health infrastructure.

NIH Activities

Dr. Souza highlighted a new public-private partnership supported by the Foundation for the NIH (FNIH) called the Bespoke Gene Therapy Consortium (BGTC), which is tasked with researching therapeutics for rare genetic diseases that affect populations too small to encourage viable commercial development. The consortium will also look to develop tools to streamline the development of gene therapies. BGTC builds on NIDCR investments in gene therapy for salivary gland disorder and should provide new opportunities to treat DOC diseases. NIDCR is also participating on NIH's Accelerating Medicines Partnership on Autoimmune and Immune-Mediated Disorders (AMP AIM), which includes Sjögren's syndrome.

Dr. D'Souza previewed the presentation on the Advanced Research Projects Agency for Health (ARPA-H) that Dr. Lawrence Tabak and Dr. Tara Schwetz. NIDCR participated actively in the listening session that NIH held on July 26 to receive input on the structure and purview of the proposed ARPA-H. Recent advances in data science, telemedicine technologies, and societal focus on health equity all suggest the importance and viability of cross-disciplinary and collaborative approaches to human health. This is particularly important in light of what the research community has learned from the COVID-19 pandemic response. The ARPA-H initiative is being led by Dr. Eric Lander, the Director of the White House Office of Science and Technology Policy (OSTP).

NIDCR Activities

Oral Health in America Report. Dr. D'Souza updated the Council on the status of the report on oral health in America. The report is a 20-year follow-up to the seminal "Oral Health in America: A Report of the Surgeon General." The new report, "Oral Health in America: Advances and Challenges," is set to be released this fall. Originally to be published by the Office of the Surgeon General, the report was delegated to NIH and NIDCR after the pandemic hit. NIDCR's stewardship and drafting process has involved extensive collaboration and solicitation of input from stakeholders. Dr. D'Souza hopes the report will catalyze efforts to address existing gaps in DOC treatment and research. For example, dental caries remain a leading childhood disease and human papillomavirus (HPV) is becoming one of the predominant causes of head and neck cancers. NIDCR plans to disseminate the report widely and strategically in order to stimulate interest in oral health and drive policies to improve oral health for all.

NIDCR Strategic Plan. Dr. D'Souza next updated the Council on the development of the 2021-2026 NIDCR Strategic Plan. The plan is designed to advance research and training priorities within the overarching theme of translation. The plan will also research the Institute's mission and vision to center core values such as diversity, equity, and inclusion. The strategic plan will also emphasize metrics and the importance of delivering results. The plan has five strategic priorities:

- Establish the cellular, molecular, behavioral, and environmental determinants that are unique to, and shared with, other systems.
- Develop more precise and individualized ways of managing and preventing DOC diseases.
- Accelerate the translation of research and the uptake of new discoveries.
- Nurture diverse future generations of oral health scientists.
- Expand already existing partnerships and create new ones.

NIDCR is currently reviewing public comments on the Strategic Plan, and hopes to release the final version by the end of the year. Dr. D'Souza said she views the Strategic Plan as a living document that can be evaluated and modified as new best practices emerge.

Other activities. Dr. D'Souza described NIDCR's diversity, equity, and inclusion (DEI) concept that has been designed under the auspices of the NIH UNITE Initiative. The concept aims to develop a strategic framework to foster diversity, equity, and inclusion in the DOC research enterprise and to engage the stakeholder community to help identify innovative strategies to advance DEI. The concept will develop a data-driven action plan and engage experts across relevant disciplines. Dr. D'Souza also highlighted NIDCR's revived Dental Public Health Residency Program, which is a three-year residency and fellowship for public health doctorates focused on oral health research. The NIDCR Temporomandibular Disorders (TMD) Working Group has completed its work and submitted its findings to the Institute on how to move the field of TMD research forward. NIDCR is currently incorporating the recommendations into the development of an action plan. Dr. D'Souza also discussed The Lancet Commission on Oral Health, which was established in 2020 in recognition of the importance of oral health to global public health and the need for a broader understanding and commitment to oral health within the global health agenda. While primarily based in Europe, the Commission will draw on findings from research based in America, including the upcoming NIDCR-published report on Oral Health in America. Dr. D'Souza said that NIDCR will strive to foster international collaboration

going forward, whether through NIH's Fogarty International Center or through its stakeholder organizations, such as IADR.

IV. PROPOSED ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH (ARPA-H)

Dr. D'Souza introduced Dr. Lawrence Tabak, NIH Principal Deputy Director, and Dr. Tara Schwetz, Assistant Director for Biomedical Science Initiatives, White House Office of Science and Technology Policy, to deliver the presentation on ARPA-H.

Dr. Schwetz opened by indicating that humanity is living through a moment of great scientific progress. In recent decades, scientists have discovered ways to harness the human immune system to fight cancer. And thanks to new technologies and research advances, the biomedical community was able to deliver safe and effective COVID-19 vaccines in an unprecedentedly short timeline. This pivotal moment has led to the question of what more can we do to accelerate the pace of medical breakthroughs and catalyze them to further improve the health of Americans? ARPA-H was proposed to lead this effort within the federal government. The House of Representatives' proposed FY22 budget appropriates $3 billion to establish this new division within NIH, although that number could change during budget negotiations on the Senate side.

Dr. Schwetz then discussed a potential draft mission statement, "To benefit the health of all Americans by catalyzing health breakthroughs that cannot readily be accomplished through traditional research or commercial activity." She described how ARPA-H is modeled on successful advanced research agencies within the federal government, most notably the Defense Advanced Research Project Agency (DARPA). In order to be successful, ARPA-H will need autonomy, resources, and authority to move independently. The goal of the agency would be to support transformative high-risk/high-reward research in order to speed application and implementation of health breakthroughs to serve all patients; accelerate breakthroughs from the molecular level to the societal; build capabilities and platforms to revolutionize prevention, treatment, and cures in a range of diseases; transform ideas into practical solutions for patients far more rapidly than previously thought possible; and to circumvent market-related hurdles through incentives and/or de-risking.

As far as its structure, ARPA-H will be connected to NIH and draw on its vast knowledge base, expertise, and infrastructure, but also remain distinct, with a unique culture and organization in order to enable risk and failure tolerance, urgency, nimbleness, and innovation. It is planned for ARPA-H to be led by a term-limited director with technical and leadership skills, who will oversee a creative and highly diverse cohort of program managers, also term-limited, who have broad autonomy in order to drive transformational change across scientific disciplines. The agency will set ambitious milestones but judge itself on quantified metrics. Dr. Schwetz emphasized that ARPA-H will be transparent about its processes and will engage stakeholders as early and often as possible. ARPA-H will develop interdisciplinary collaborations across academia, industry, NIH ICs, and its sister agencies in the federal government.

Dr. Schwetz next discussed some of the unique authorities ARPA-H will need to accomplish its mission. For example, it must be able to rapidly hire staff outside of the civil service system and offer competitive wages. In order to create the requisite sense of urgency, it will recruit expert project managers for short, three- to five-year terms. ARPA-H will need broad and flexible funding authorities and must be able to select and manage its projects with minimal bureaucracy.

Finally, Dr. Schwetz described NIH and OSTP's recent outreach efforts to gather feedback on ARPA-H from stakeholders, including a series of listening sessions that involved over 5,000 participants and 250 organizations in total. A summary report is being drafted on the listening session feedback, which will be released in the coming weeks. Some of the major themes from the sessions are that ARPA-H should supplement NIH's research portfolio but not duplicate it, the importance of addressing health inequities, leveraging artificial intelligence, and using commercialization to get products to patients quickly, among other themes.

Discussion

Dr. D'Souza expressed NIDCR's eagerness to collaborate with the future ARPA-H, particularly given oral health's centrality to overall human health. Dr. Axel Visel asked Dr. Schwetz to comment on lessons that NIH can draw from the other ARPA projects. Dr. Schwetz said that DARPA, for example, is unique in that it has a built-in customer for its products in the U.S. military, which it can collaborate with at all levels of its activities. This will not quite be the case for ARPA-H and its structure will have to be adjusted accordingly. Ms. Diana Rutberg asked what the timeline for ARPA-H looks like past 2021. Dr. Schwetz said the goal is to start making initial awards in FY22, hopefully supported by multi-year funding. In response to a question from Dr. Raul Garcia, Dr. Schwetz confirmed that population health will be built into ARPA-H's approach. In further discussion, Dr. Schwetz emphasized that ARPA-H will be disease-agnostic and attempt to develop platforms and capabilities with a broad impact. For example, mRNA vaccines have proven highly successful in the fight against COVID-19 and are being used for other diseases. ARPA-H might work to discover the next game-changing vaccine platform. Dr. Joel Strom asked whether clinicians will have a role in ARPA-H in order to help keep the research grounded. Dr. Schwetz said that ARPA-H will focus on use-driven research with practical applications.

V. CONCEPT CLEARANCE

Dr. Dombroski, Director, DEA, stated that NIDCR is required to present the purpose, scope, and objectives of proposed concepts for research initiatives to the Council in a public forum for the Council's review, discussion, and approval, and for public comment. Concepts approved by the Council are published on the NIDCR website (future research initiatives). NIDCR staff presented 11 concepts, and designated Council members led the discussion, as summarized below.

In utero Treatment of Congenital Dental and Craniofacial Disorders Using Precision Medicine Approaches

Dr. Lu Wang, Chief, Translational Genomics Research Branch, DER, presented the concept. The goal of the concept is to "accelerate the development of *in utero* treatments for congenital dental and craniofacial disorders using animal models and precision medicine approaches." Congenital disorders have been associated with specific risk and causal factors that are genetic, epigenetic, nutritional, and environmental, and if left untreated, are often irreversible. There is currently a lack of *in utero* treatments for most human congenital dental and craniofacial disorders, but new precision medicine approaches and availability of new gestational diagnostics offer a new opportunity to address this gap. The concept will consider a variety of treatment approaches, delivery modalities, and will conduct studies using both small and large animal models.

The Council's lead discussants for the concept were Drs. Nor and Visel. Dr. Nor said he believes this concept to be timely and important. In addition to potentially developing treatments to DOC disorders, this initiative might also lead to the development of platforms that could be used to treat many other genetic conditions. He advised researchers to bear in mind bioethical implications of *in utero* treatments to human DOC disorders. Dr. Visel said he was excited about the concept's potential to lay the foundation for transformative approaches. He sees this as the type of high risk/high reward research that NIDCR should be supporting. Dr. Visel noted that while there have been advances in gestational diagnostics, in many cases disorders still cannot be observed early enough for treatment to be viable. He recommended incorporating and integrating diagnostic research into the concept.

The Council unanimously approved the concept.

Spatiotemporal Mapping of Craniofacial Embryogenesis at the Single-Cell Level

Dr. Katie Stein, Developmental Biology and Genetics Program, DER, presented the concept. The goal of this initiative is "to encourage investigators to apply recent advances in spatial transcriptomics, imaging, and high-throughput single-cell sequencing approaches to understand the complex spatiotemporal context of the developing embryo." Dr. Stein described how there are major knowledge gaps in science's understanding of the spatiotemporal dynamics of cell populations in dental and craniofacial development. In the last decade, advances in genomics have made it possible to learn the transcriptional profile of a selected tissue. Over the last several years, the use of single-cell RNA-sequencing has become a routine tool for obtaining a snapshot of genomic-level events occurring in groups of dissociated cells, but there is a lack of understanding in how this information maps back to the landscape of the embryo. The overall objective of this concept is to encourage the research community to leverage cutting-edge technologies to map the embryonic developmental landscape and develop a more integrated understanding of craniofacial and dental development.

The Council's lead discussants for the concept were Dr. Kathryn Albers and Dr. Lee Niswander. Dr. Albers expressed support for the concept, particularly noting how it complements the *in utero* treatment concept that was just discussed and addresses one of NIDCR's strategic priorities. Recent technological advances make this concept very timely. As in many other biomedical research projects, data integration will be a challenge. Data sharing and collaboration

should also be key principles. Dr. Niswander seconded Dr. Albers' comments, noting that the increased availability of the technologies in question should facilitate broader collaboration. Dr. Visel encouraged the concept to look beyond the cellular level to, for example, genes and regulatory sequences. He also recommended that the concept use FaceBase to facilitate the data sharing aspects.

The Council unanimously approved the concept.

The Functional Oral Microbiome

Dr. Tamara McNealy, Director, Oral Microbiota and Bacterial Disease Program, DER, presented the concept. This initiative is designed to encourage multidimensional research that explores the interconnectedness and uniqueness of the oral microbiome in order to broaden understanding of the mechanisms underlying the stability, persistence, and resistance of the oral microbial community. The oral microbiome has been well-studied, but most research to-date has focused solely on the bacteriome. This concept hopes to encourage research looking at the microbiome community as a whole and its role in the maintenance of health and the transition to dysbiosis and disease in the oral cavity. This will hopefully lead to insights on oral microbiome transplants and treatments. Dr. McNealy expects this concept to fund multi-'omics approaches that utilized metabolic interaction models and/or ex vivo synthetic biofilm systems.

The Council's lead discussants for the concept were Dr. Joel Collier and Dr. Wenyuan Shi. Dr. Shi said he was highly enthusiastic about this initiative and the notion of moving beyond the bacteriome is considered a consensus next step by the research community. Dr. Collier agreed with Dr. Shi's remarks and expressed his particular excitement about the biomaterials, devices, and transplantation aspects. Dr. Strom advised NIDCR to consider down-the-road state-level scope of practice issues that may hinder on-the-ground application in certain locales.

The Council unanimously approved the concept.

Characterizing Novel Mechanisms to Advance the Science of Behavior Change in Oral Health

Dr. Elise Rice, Program Officer, Behavioral and Social Sciences Research Branch, DER, presented the concept. The aim of the program is to generate research that "characterizes and evaluates novel behavioral and social mechanisms of action relevant to dental and oral health, as well as the whole health and wellbeing of people with DOC conditions." Ultimately, the concept is designed to lead to thorough and actionable behavioral science of oral health and lead to more informed decision-making on the deployment of interventions. Previous research on psychological processes has generally focused on topics that are conscious, deliberate, or intentional, such as knowledge or attitudes, rather than non-conscious or affective processes, interpersonal processes, and social, cultural, and policy-related factors; i.e., the broader realm of causal mechanisms that influence oral health behavior. Achieving a better understanding of the precise mechanisms that govern oral health behavior and the related contextual parameters that influence them should facilitate more efficient and rapid implementation of scientific developments. Potential areas of research might include patient-provider communication, habit formation, group dynamics, or structural barriers that present hurdles to oral health.

The Council's lead discussants for the concept were Dr. Strom and Dr. Amy Smith Slep. Dr. Strom noted that the concept was written broadly on purpose so as to not restrict potential research projects given the broad scope of potential avenues for exploration. He said the concept fits well into the NIDCR Strategic Plan priority of studying health equity factors and dental care aversion. Dr. Strom again raised the issue of state scope of practice laws and the need to ensure that interventions that arise from NIDCR concepts can reach the dental chair. Dr. Slep expressed strong support for the concept. She praised the effort to bring together the prevention, behavior, and implementation sciences with oral health research; the latter has usually been missing from the former disciplines. Dr. Garcia asked whether the behavior research will include care provider behavior as well as patient behavior. Dr. Rice said her hope is that the research will include the behavior of all parties relevant to the clinical setting. Dr. Slep said she sees space in the concept for research on dental provider communication, communication training, as well as parents and the local community, among other fruitful areas of study.

The Council unanimously approved the concept.

Oral Health Promotion Using Technologies Outside the Dental Setting

Dr. Melissa Riddle, Chief, Behavioral and Social Sciences Research Branch, DER, presented the concept to the Council. Dr. Riddle began by stating that she sees this concept as connected to the previous concept in that it expands beyond individual-level behavior. The initiative hopes to leverage emerging technologies and lessons learned from the public health response to the COVID-19 pandemic, climate change, and other natural disasters. Overall, the goal of the concept is "to encourage research that develops, adapts, and/or tests technology-facilitated behavioral, community, and organizational tools for use in oral health promotion outside of the dental clinic." This will occur by harnessing existing technologies, strengthening the evidence base for various tools and approaches, extending capacity for oral health promotion services, and improving access and equity. Some examples of projects might include, but are not limited to, testing existing internet- or phone-based oral health promotion interventions, developing new technology-facilitated outreach models for underserved communities, testing remote monitoring and communication systems, conducting studies that compare the efficacy of technology-based promotion to in-person oral health promotion, or establishing platforms for electronic health record integration.

The Council's lead discussants for the concept were Dr. Frank Ebetino and Dr. Raul Garcia. Dr. Ebetino expressed support for the initiative. Given the universe of potential oral health promotion approaches, he recommended focusing on those that address access among underserved communities for the greatest impact. Dr. Garcia expressed enthusiastic support for the program. Dr. Garcia also was supportive of the concept, which is timely and addresses important gaps and opportunities. He expressed the concern that the concept may be overbroad and advised NIDCR to exercise caution when considering applications that may meet the letter of the concept but perhaps not its spirit. For example, NIDCR might consider teledentistry applications since that assumes a pre-existing dentist-patient relationship that is often lacking in underserved communities. He also encouraged NIDCR to support research in this area that makes a clear connection between behavior change and improvements in oral health.

The Council unanimously approved the concept.

Advancing HIV/AIDS Research at the Intersection of Mental and Oral Health

Dr. Hiroki Iida, HIV/AIDS & Oral Health Research Program, DER, presented the concept. Dr. Iida began her talk by noting that individuals living with HIV are at higher risk for mental health and co-occurring behavioral disorders, including drug abuse, than those who do not have HIV. Research has shown that mental illnesses are also linked to poorer oral health outcomes, but the underlying mechanisms remain largely unknown. The goal of this initiative is to solicit research to help better understand the basic biological, psychosocial, and behavioral factors that contribute to mental and oral health interactions in the context of HIV. Over the past decade, there has been little research focused on mental and oral health in people living with HIV. Potential research topics under this concept might include studies on the combined impact of antiretroviral therapy and psychiatric pharmacotherapy on oral health and wellbeing, social determinants of health that influence mental and oral health outcomes, or the independent and interactive effects of mental illness and co-occurring conditions on oral health outcomes, among others.

The Council's lead discussants for the concept were Drs. Slep and Albers. Dr. Slep said she was supportive of the concept and complimented its objective to break down the silos of mental health and oral health. Dr. Albers concurred with Dr. Slep's comments and suggested that the concept attempt to incorporate the interactions between mental health and pain.

The Council unanimously approved the concept.

Data-Driven Tools to Accelerate the Clinical Translation of Novel Dental, Oral, and Craniofacial Biomaterials

Dr. Orlando Lopez, Director, Dental Materials and Biomaterials Program, DER, presented the concept, which is a partnership with NIDCR's Data Science, Computational Biology, & Bioinformatics Program. The goals of this initiative are twofold: 1) to accelerate clinical translation of novel biomaterials through the development of data-driven tools that address complexities and inefficiencies in critical steps of biomaterials research and development (R&D), and 2) to facilitate the regulatory approval and in-human use of new biomaterials by leveraging the FDA Medical Device Development Tools (MDDT) framework. This concept is designed to confront the problem that R&D for DOC biomaterials is currently cost-prohibitive and time to market can take over a decade. One contributing factor to the R&D bottleneck has been the limited adoption of data-driven tools in biomaterials R&D. Advances in data science mean that now is an opportune time to leverage data resources and cross-disciplinary expertise. Data-driven characterization models and assessment tools developed under this concept might study the durability of dental materials in the oral environment, early biocompatibility risks and toxicity degradation byproducts, or failure-mode determination and design optimization, among many others. Utilizing the FDA's MDDT program provides a dedicated and effective pathway for evaluation and qualification of data-driven tools for specified use contexts.

The Council's lead discussants for the concept were Drs. Couper and Visel. Dr. Visel said he was excited about this concept in light of major recent advances in computer science, machine learning, and artificial intelligence. Application of these concepts in the field of biomaterials holds great promise. Dr. Visel encouraged NIDCR to be clear about what it means by biomaterials, as this term can have broader or narrower definitions. It is his understanding that biomaterials point to any material used in biological applications for the purposes of this concept, rather than more narrow definitions, and this should be spelled out in the concept. Dr. Visel also encouraged the concept team to consider how computational aspects are integrated into the entire product design and testing cycle. Dr. Couper said he was most excited about how the concept stimulates collaborative science, including data scientists, materials researchers, and regulators. Dr. Couper asked Dr. Lopez to comment on the availability of data sets or whether researchers will be required to generate their own data sets. Dr. Lopez said relevant data sets of biomaterials information are available through various federal agencies, including NIH, NSF, NIST, as well as from data repositories associated with societies focusing on biomaterials research.

The Council unanimously approved the concept.

Advancing Diversity, Equity, and Inclusion in the Dental, Oral and Craniofacial Workforce

Dr. Leslie Frieden, Research Training and Career Development Branch, DEA, presented the concept. The goal of this initiative is to engage a broad range of stakeholders in developing a strategic framework to advance diversity, equity, and inclusion (DEI) in the NIDCR DOC research enterprise. The strategic framework will provide the foundation for a comprehensive action plan with bold recommendations on how best to implement DEI programs and activities across a range of career pathways that ultimately grow and sustain a diverse DOC research workforce striving to improve health for all individuals and communities. Dr. Frieden described how this concept will complement existing NIDCR research training programs and research supplements focused on diversity. NIDCR will engage a broad array of organizations across academia, industry, professional societies, and private foundations, and will include experts in DOC, DEI, mentoring, and outreach. The concept will solicit grants across all career stages, with a particular emphasis on engaging undergraduate students to enter DOC research tracks in dental school or doctoral degree programs.

The Council's lead discussants for the concept were Drs. Ebetino, Niswander, and Nor. Dr. Niswander expressed support for the concept, noting that it addresses NIDCR's priority of developing strategies to increase the diversity of scholars in DOC research. She listed some potential stakeholders of interest and recommended that NIDCR consider partnering with the National Institute of General Medical Sciences (NIGMS) on training grants focused on the undergraduate level. Dr. Ebetino also expressed support for the concept and the potential for better science to emerge from more diverse research teams. He emphasized the importance of training and perpetuating expertise within these diverse teams. Dr. Nor concurred with Dr. Ebetino's comments and added his opinion that NIDCR should consider socioeconomic diversity in this concept, as well. He was excited about the focus on the undergraduate level and suggested expanding to include high school in order to reach potential future scholars even earlier.

The Council unanimously approved the concept.

Short-term Mentored Career Enhancement Award in Dental, Oral, and Craniofacial Research for Mid-Career and Senior Investigators (K18)

Dr. Lynn King, Chief, Research Training and Career Development Branch, DEA, presented the reissuance concept. The goal of this program is to help build a robust and diverse DOC research workforce by providing career development opportunities for mid-career and senior investigators. Dr. King described the other grants NIDCR offers for established investigators, which include the F33 and K25, and discussed how the K18 concept fills a gap for mid-career investigators by providing flexibility in effort commitment and duration of support (2.5 months to 12 months). To date, the K18 program has received 8 applications and 2 awards have been granted in the research areas of bioinformatics and the oral microbiome.

The Council's lead discussants for the concept were Drs. Niswander and Shi. Dr. Niswander said both discussants were supportive of the concept. They were surprised by the small number of applicants so far and hoped the inclusion of industry experience would spur interest.

The Council unanimously approved the concept.

NIDCR Dental Specialty PhD Program (DSPP) (K12)

Dr. King presented the reissuance concept. The goals of this program are to recruit, educate, and train future scientific leaders in academic dentistry by supporting a combined Dental Specialty and PhD Program (DSPP) for early career dentist scientists, and to maintain a critical mass of investigators with knowledge of DOC biology who can participate in multidisciplinary research teams. Dr. King described the structure of the DSPP and the statistics of the first pilot cycle of the program. NIDCR received 8 applications and funded 3 awards with two scholars funded per award.

The Council's lead discussants for the concept were Drs. Stanford and Strom. Dr. Strom expressed his support for the reissuance and praised the flexibility of the program, which he believed will encourage more applicants over time. Dr. Stanford was also supportive but recommended that NIDCR require a clear governance model in order to help resolve potential conflicts between the clinical and academic research faculty. He also felt the concept should more strongly encourage applicants to present a clear connection between the clinical and PhD components of their proposed programs. Dr. Strom asked if NIDCR has any role to play at the placement stage, after this program has been completed. Dr. King said NIDCR does have further funding opportunities at the independent research stage, such as K99/R00, the Career Development Award, and other transition awards. Dr. Nor suggested that NIDCR consider including some non-ADA-approved specialties, such as cariology and restorative dentistry. The Council discussed the need to provide support for dental scholars at a difficult career stage that can often be financially challenging, particularly for those from underrepresented backgrounds. Dr. King agreed, and pointed to NIH's Loan Repayment Program, which repays up to $50,000 per year for approved researchers, as one way NIH tries to provide financial assistance in this regard.

The Council unanimously approved the concept.

NIDCR-NCATS Clinical and Translational Science Award KL2 Partnership Program

Dr. King presented the concept. The goal of this reissued concept is to leverage expertise and resources available in Clinical and Translational Science Award (CTSA) programs supported by the National Center for Advancing Translational Sciences (NCATS) for clinical and translational research training experiences for DOC scholars, who have been underrepresented in the CTSA program since its creation. This will help train DOC scholars in the principles and skills of translational science, foster team science across a broad range of scientific disciplines and enhance the development of a well-trained and skilled translational DOC research workforce. The pilot program began in 2017, for which NIDCR received 15 applications and ultimately funded 5 awards.

The Council's lead discussants for the concept were Drs. Garcia and Stanford. Dr. Garcia was highly supportive of the concept which he believes will deliver a high return on investment. Dr. Stanford agreed and said the CTSA program is a vital way for a smaller IC like NIDCR to expand its influence at research institutions.

The Council unanimously approved the concept.

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 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

VI. REVIEW OF APPLICATIONS

The Council considered 634 applications requesting $204,200,242 in total costs. The Council recommended 391 applications for a total cost of $127,523,735.

VII. ADJOURNMENT

CERTIFICATION

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

/Rena D'Souza/
Dr. Rena D'Souza
Chairperson
National Advisory Dental and
Craniofacial Research Council

/Alicia Dombroski/
Dr. Alicia Dombroski
Executive Secretary
National Advisory Dental and
Craniofacial Research Council

ATTACHMENTS

I. Roster of Council Members