

March 15th, 2023

Rena D'Souza, DDS, MS, PhD Director, Building 31, Room 2C39 Center Drive, MSC 2290, Bethesda, MD 20892 USA

Re: National Institute of Dental and Craniofacial Research's Request for Information on Reissuance of Prospective Observational or Biomarker Validation Study Cooperative Agreement.

via website: https://www.nidcr.nih.gov/grants-funding/funding-priorities/future-research-initiatives-concept-clearances/january-2023-input-request?utm medium=email&utm source=govdelivery

The American Association for Dental, Oral, and Craniofacial Research (AADOCR) represents over 3,100 individual and 107 institutional members working throughout dental, oral, and craniofacial research. We appreciate the opportunity to share our thoughts on the request for information on the reissuance of prospective observational or biomarker validation study cooperative agreement. AADOCR recognizes and applauds the National Institute of Dental and Craniofacial Research's (NIDCR) efforts towards supporting resource intensive research proposals that require long-term data and analysis in large cohorts. To respond to this request for comments, AADOCR engaged its Science Information Committee and its Board of Directors.

AADOCR would like to congratulate NIDCR on a funding opportunity announcement (FOA) series that has funded more than 10 applications with an overall 52 percent award rate. The productivity of the awardees has also resulted in over 30 publications including the dissemination of the results and data from the projects. It is even more encouraging that awardees included early-stage new investigators and that projects comprised of multiple project investigators. *AADOCR supports the reissuance of this important cooperative agreement* to foster applications that may further explore prospective cohort and biomarker validation studies that cover a wide breadth of craniofacial diseases or conditions. This FOA is undoubtedly a very valuable mechanism for leveraging ongoing studies and/or data.

AADOCR supports the consideration of the separation of this FOA into two announcements to provide increased funding for prospective cohorts to include more groups across sex, age, and racial/ethnic/ancestral diversity within their analyses. A prospective cohort study allows the investigators to carefully measure the hypothesized exposures long before their effects are manifested in the disease state¹. Cohort

discovery studies that are comprised of a heterogeneous cohort provide for greater population generalizability to the general population and are more appropriately powered^{2,3,4}. These data can then be validated in separate biomarker studies with equally diverse cohorts. A more heterogeneous cohort may also discern biomarkers that are useful only in some sexes, in some age groups, and in some racial/ethnic/ancestrally diverse backgrounds and allow for a greater understanding of how clinical-level data can impact disease course. In the event that the release of two financially robust FOAs is not feasible, AADOCR supports instituting a mechanism for linking the two types of grants/studies where upon successful completion of the prospective cohort, a subset can then advance to validation.

Research capacity building and research and development participation challenges often hinder researchers from community colleges, minority servicing institutions (MSIs), historically black college or universities (HBCUs) from establishing and maintaining robust scholarly and scientific agendas at these institutions⁵. Therefore, AADOCR encourages being very inclusive in the outreach and selection of applicants of this FOA by intentionally including researchers from within underrepresented groups. Additionally, AADOCR encourages NIDCR to include mentoring of undergraduate students as a component of this FOA. This may serve to create a longitudinal cohort for enrichment in DOC research that would also generate data on the impact of enrichment programs on learning. This is especially important for the training of researchers from underrepresented populations as underrepresented minority (URM) faculty often receive less mentoring than their nonminority peers⁶.

AADOCR appreciates the opportunity to provide comments on the request for information on the Reissuance of Prospective Observational or Biomarker Validation Study Cooperative Agreement. AADOCR stands ready to work with NIDCR to advance fundamental knowledge about DOC health and disease and translate these long term data findings and analyses into prevention, early detection, and treatment strategies that improve overall health for all individuals and communities across the lifespan.

If you have any further questions, please contact Dr. Makyba Charles-Ayinde, Director of Science Policy, at mcayinde@iadr.org.

Sincerely,

Christopher H. Fox, DMD, DMSc

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¹Paneth N, Monk C. (2018). The Importance of Cohort Research Starting Early in Life to Understanding Child Health. Curr Opin Pediatr. 30(2):292-296. doi: 10.1097/MOP.000000000000596.

²Grosskurth, Heiner, and Lilani Kumaranayake. (2009). Effective Sexual Health Interventions: Issues in Experimental Evaluation. Oxford Academic. Retrieved from: https://doi.org/10.1093/acprof:oso/9780198508496.003.0011. [Accessed on Mar 8, 2023].
³Dziadkowiec, O. (2021). Use of Statistical Power Analysis in Prospective and Retrospective Research. *Journal of*

Obstetric, Gyncologic, and Neonatal Nursing. 50(2):119-121.

⁴B Kukull WA, Ganguli M. (2012). Generalizability: the trees, the forest, and the low-hanging fruit. *Neurology*. 5;78(23):1886-91.

⁵Manyibe EO, Moore CL, Aref F, Sagini MM, Zeng S, and Alston RJ. (2017). Minority-Serving Institutions and Disability, Health, Independent Living, and Rehabilitation Research Participation Challenges: A Review of the Literature and Policy. Rehabilitation Research, Policy, and Education, 31:174-193.

⁶Beech BM, Calles-Escandon J, Hairston KG, Langdon SE, Latham-Sadler BA, Bell RA. (2013). Mentoring Programs for Underrepresented Minority Faculty in Academic Medical Centers: A Systematic Review of the Literature. Acad Med. 88 (4):541-9.