AADOCR
American Association for Dental, Oral, and Craniofacial Research

April 17, 2026

Unsolicited Clinical Trials Specific Application Form Working Group,
National Institutes of Health,
6705 Rockledge Drive, Suite 630,
Bethesda, MD, 20817

Re: Request for Information on Draft NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy.

via website: https://rfi.grants.nih.gov/?s=6998c6f85af314d3d80c0b72

The American Association for Dental, Oral, and Craniofacial Research (AADOCR) is the leading professional community for multidisciplinary scientists who advance dental, oral, and craniofacial research. We appreciate the National Institutes of Health (NIH)'s efforts to reduce administrative burden and improve the clarity, consistency, and reviewability of investigator-initiated clinical trial applications. To respond to this request for comments, AADOCR engaged its Science Information Committee.

The organization of required content around the core elements of trial design, conduct, and oversight will likely improve navigation within clinical trial applications. Therefore, **AADOCR supports the proposed changes**, as they are likely to promote more consistent formatting, reduce duplication, and facilitate review without materially increasing burden. The proposed approach would benefit both dental, oral, and craniofacial (DOC) researchers and reviewers. Clinical trial applications within the DOC space often involve behavioral interventions, devices, procedures, prevention strategies, community-based approaches, and multi-site or pragmatic designs. Under the current application framework, important details may be distributed across both the narrative Research Plan and the Human Subjects and Clinical Trials Information Form. Therefore, the proposed consolidated form should reduce fragmentation, make essential information more prominent, and improve both efficiency and consistency of review. Additionally, **AADOCR also supports the proposed form's consistency and alignment with established clinical trial reporting frameworks**.

AADOCR also encourages NIH to preserve a limited mechanism for trial-specific clarification. An additional section or field would allow investigators to provide clarifying information specific to the design of their trial when needed. An optional section would preserve flexibility for studies that do not fit neatly into standard categories or where a rigid structure may not fully capture features important to scientific merit or operational feasibility. Additionally, the proposed overall page limit may be plausible for many studies, however some complex multi-site or highly regulated trials may be unable to adequately address required considerations within

those constraints. Therefore, once the proposed form is instituted, **AADOCR supports an analysis of whether certain categories of trials are disproportionately affected by the page limit**.

Furthermore, as NIH develops the instructional text, **AADOCR supports the inclusion of clear guidance on the expected level of detail for each section**, particularly to distinguish application-level expectations from protocol-level detail. Investigators would especially benefit from examples illustrating the appropriate level of specificity to reduce unnecessary over-writing, improve consistency across applications, and lessen burden for both applicants and reviewers.

AADOCR appreciates NIH's effort to strengthen the clinical trial application process. We would welcome continued engagement as NIH refines the instructional text and creates implementation and training guidance for investigators, peer reviewers, and institutional grants offices.

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
Chief Executive Officer

Nisha D'Silva, BDS, MSD, PhD
President