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Re: NIH Request for Public Comment on Draft Protocol Template for Behavioral and Social Sciences Clinical Trials (NOT-OD-18-167)

Dear Drs. Wolinetz and Riley:

On behalf of the 3,400 individual and 103 institutional members of the American Association for Dental Research (AADR), thank you for the opportunity to submit comments on “Draft Protocol Template for Behavioral and Social Sciences Clinical Trials”. To prepare these comments, we consulted AADR’s Behavioral, Epidemiologic and Health Services Scientific Group, whose members promote and encourage research in behavioral, epidemiologic and health services sciences in the areas of epidemiology of oral diseases and their prevention, social inequalities, behavioral dentistry, health professions and public education, evidence-based policy interventions, population-based observational and interventional studies and community-based participatory action research. This group represents over 300 AADR members, and given the interdisciplinary nature of research, this clinical trial template is important to advancing dental, oral and craniofacial research and bringing research discoveries to patients.

In general, this template was very well received with almost all positive comments. It is quite helpful to have a revision of the NIH Clinical Trial Template that is specifically modified to be inclusive of behaviorally- and socially-based interventions. The specificity of the document and the embedded explanatory language (e.g., objectives and endpoints) is user-friendly. The plan to integrate the final behavioral and social sciences protocol template into the existing e-Protocol Writing Tool is an excellent plan and will be quite helpful to investigators.

Regarding the clarity of the document, there is one sentence in section 5.3 that may be difficult to understand: “Describe what action will be taken if prohibited medications, treatments or procedures are indicated for care (e.g., early withdrawal).” It is
unclear what “indicated for care” would mean. Does withdrawal refer to withdrawal under a participant’s decision or withdrawal at the direction of the investigators?

The “Administration of questionnaires or other instruments for patient-reported outcomes, such as a daily diary” section seems rather basic. Verbal report instruments can be administered on paper or via question-asking by an investigator. These same approaches can be administered to significant others (e.g., spouses) or to health professionals providing care to the research participant. Furthermore, structured and semi-structured interviews also can be administered pre- and post-intervention, which should be specifically mentioned as well.

Moving forward, it would be very helpful to have a sample completed protocol available online that would provide an example for a behavioral/social science intervention.

Thank you for the opportunity to provide feedback and for your thoughtful consideration of these comments. We stand ready to work with your office as this template is finalized. Please do not hesitate to contact Director of Science Policy and Government Affairs, Dr. Seun Ajiboye, at sajiboye@iadr.org with any further questions.

Sincerely,

Christopher H. Fox, DMD, DMSc
Chief Executive Officer

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President