MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

January 17, 2019

The Honorable Alex M. Azar II
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Healthy People 2030

Dear Mr. Azar,

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) appreciates the opportunity to submit public comment on the U.S. Department of Health and Human Services (HHS) Healthy People 2030 objectives.

The MRCT Center is a research and policy center focused on improving the design, conduct, and oversight of multi-regional clinical trials, with a particular focus on multi-site, transnational trials. Our efforts have resulted in the implementation of improved clinical research practices, greater transparency, and improved safety for research participants. We function as an independent convening group to bring together collaborative multidisciplinary teams to identify expert stakeholders from industry, academia, advocacy groups, nonprofit organizations, and regulatory agencies to address critical issues in the conduct and oversight of clinical trials.

The MRCT Center fully supports the mission of Healthy People 2030, aiming "to promote, strengthen and evaluate the Nation's efforts to improve the health and well-being of all people." The objectives outlined in the report are crucial components to the health of our nation – in particular the objectives under the topic areas of "Access to Health Services," "Health Communication and Health Information Technology," and "Social Determinants of Health" that all strive in some way to make health information more accessible, understandable, and focused to groups that are most vulnerable and underserved.

Clinical research is an essential element of developing the evidence base for health promotion. We encourage HHS to consider Clinical Research as a new topic area within Healthy People 2030 and to develop concrete objectives that promote clinical research as foundational to health promotion and disease prevention. Improvements in the health and well-being of individuals will require systematic inquiry. A data driven approach to expand the evidence base is critical to successful attainment of these noble goals. As such, we recommend a renewed focus (1) on health literacy, specifically as it pertains to making research more understandable and accessible to the American public and (2) on diversity to ensure that that clinical research studies include, and findings represent, the diversity of the population of America. We discuss each focus briefly and realize that the data sources to which we refer below may need to be refined for the intended purpose.

1) Health Literacy

Health literacy is a shared responsibility between the researcher and potential participant and involves a relationship that supports autonomous, value-concordant participant decision-making. As such, the participant must understand the nature of clinical research and the details of the specific research project that they are considering and specifically how the research differs from the care they would otherwise receive. The commitment to health literacy in clinical research includes readability, use of plain language, and techniques that support processing of numeric data, visualization of information, use of appropriate images and design techniques, and cultural awareness. We note, however, that while health literacy remains a "foundational principle" of Healthy People 2030, the proposed topic areas surprisingly no longer include health literacy objectives to which to work. We encourage reinstatement of health literacy objectives from Healthy People 2020 (for example, HC/HIT-1), in addition to health literacy clinical research developmental and research objectives, such as:

- Increased access to clinical research study information by improving compliance with and understandability of ClinicalTrials.gov reporting as required by FDAAA and the 21st Century Cures Act. In our opinion, reporting should include a plain language summary that is accessible to the public. The data source for reporting of clinical research study results is ClinicalTrials.gov - developmental objective.
- The application of health literacy principles in informed consent forms measured via inclusion of standard readability assessment data as a proxy for understandability. The data source for informed consent forms may be ClinicalTrials.gov; a validated readability tool can be applied to or available at ClinicalTrials.gov – research objective.
- Increased trust and transparency via the provision of aggregate clinical research study results summaries, commonly known as lay summaries, to all participants at the end of their study participation that include a link to ClinicalTrials.gov for additional objective results data. The source of this data is, as of yet, unknown - research objective.

2) Diversity

Worldwide, regulatory approvals for investigational products are based on carefully designed, blinded, randomized clinical trials. To provide generalizable knowledge, the participant population enrolled in clinical trials should reflect the composition of the general population or those affected by the disease. However, often this does not happen. This failure to achieve meaningful diversity limits information about drug response and measures of safety and efficacy in historically under-represented and under-studied populations, in particular women, ethnic and racial minorities, children, and the elderly.

As such, a few goals to consider for increasing diverse representation in clinical trials and research include:

- Increasing the participation of diverse populations, including ethnic and racial minorities, women, individuals at either end of the age spectrum, individuals of lower socioeconomic class, and others in clinical trials. The data sources for the demographics of clinical trial participants are ClinicalTrials.gov and FDA Clinical Trial Snapshots – core objective
- Increasing the proportion of participants in clinical trials that are most affected by the particular disease condition, based on prevalence and incidence rates. The data source for disease prevalence can be data from Agency for Healthcare Research and Quality [AHRQ] and the number of and demographics of clinical trial participants are ClinicalTrials.gov and FDA Clinical Trial Snapshots – core objective.

- Increasing and standardizing the collection of data variables used in clinical trials, including variables within the social determinants of health such as socioeconomic status, education, health insurance, geographic location/region, gender identity, disability status, health literacy, ancestry, place of birth, etc. The data sources are AHRQ, ClinicalTrials.gov and FDA Clinical Trial Snapshots, with recommendation to further standardize the collection of demographic data elements – developmental objective.
- Increasing the proportion of institutions and organizations that have policies requiring diverse and inclusive participant population in their clinical trials and research. The source of this data is, as of yet, unknown– research objective.
- Increasing the percentage of professionals from ethnic and racial minorities in the clinical trials workforce. The source of this data is, as of yet, unknown – research objective.

Thank you again for the opportunity to comment on this important issue. We are available to discuss our comments with you if that would be helpful and would be happy to work with you on any of the aforementioned items. Please feel free to contact the MRCT Center leadership at the email addresses listed below or at mrct@bwh.harvard.edu.

Respectfully submitted,

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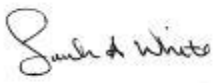

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