

**The EDICT Credo**

The following beliefs guide our work together:

All individuals will have the opportunity and necessary support to participate voluntarily in clinical trials for which they are eligible.

Participants and researchers will understand and promote the benefits of diversity in clinical trials.

Results from clinical research will benefit the participants' communities and society at large.

Dear EDICT Collaborator,

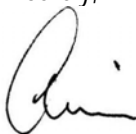
On Wed. October 17, CMS issued its Decision Memorandum on its Clinical Trials Policy ("CTP"). In this Memorandum, CMS determined that no change to the July 9, 2007 CTP was warranted at this time. In its own words, CMS based its decision "on a thorough review and consideration of comments from the public and the recent enactment of the Food and Drug Administration Amendments Act of 2007."

In the Questions and Answers document that accompanied the Oct. 17 Decision Memorandum, CMS noted that existing coverage is neither changed nor eliminated. Routine costs will be covered under the July 9 CTP. CMS also explained in its Oct. 17 Questions and Answers document that it was continuing uninterrupted the previous "deeming" process, and was not supplementing the process with the "self-certification" requirements as described in the July 19<sup>th</sup> memorandum.

The changes that CMS proposed included specific language pertaining to disparities in clinical trials. We on the Eliminating Disparities in Clinical Trials Project Team appreciate the conversation on this issue that CMS's efforts promoted across a variety of stakeholders. Such discussion is crucial in highlighting ways in which coverage concerns produce or exacerbate such disparities. CMS's clinical trial policy will only grow in significance as the U.S. population ages and its diversity increases, especially because the elderly at present are dramatically underrepresented in clinical trials.<sup>1</sup> Because these disparities undermine both the quality of the evidence produced in the research<sup>2</sup> and the justness of it, policy priorities should ultimately promote inclusion of covered persons and maximum reimbursement of covered costs.

We are gratified to have engaged CMS and other stakeholders on these important issues, and believe that further discourse on coverage, social justice, and clinical trials is warranted. The EDICT Team looks forward to participating in subsequent conversations on CMS's clinical trials policy, and would be pleased to provide a forum for open discussion in the coming months.

Sincerely,



Armin D. Weinberg, PhD  
Principal Investigator-EDICT

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<sup>1</sup> See, e.g., Vivek H. Murthy et al., *Participation in Cancer Clinical Trials: Race-, Sex-, and Age-Based Disparities*, 291(22) JAMA 2720 (2004); J.H. Lewis et al., *Participation of Patients 65 Years of Age or Older in Cancer Clinical Trials*, 21(7) J. CLIN. ONCOLOGY 1383 (2003).

<sup>2</sup> See, e.g., Antronette K. Yancey et al., *Effective Recruitment and Retention of Minority Research Participants*, 27 ANN. REV. PUB. HEALTH 1 (2006).