Cooperative Research Ethics Review Boards: A Win-Win Solution?

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Enhancing public participation in research is one of the central challenges facing the clinical research enterprise in the United States, and one of its highest priorities. Public concern about the safety of participating in research is increasing, reflected in a rising tide of litigation, negative articles in the popular press, and other published commentaries. Part of this concern focuses on Research Ethics Review Boards (Research ERBs)—the entities responsible for ethical review and oversight of human research. These bodies, referred to in federal regulations as Institutional Review Boards (IRBs), are overburdened and often characterized as inefficient and ineffective. The increasing number of multi-center studies is exacerbating current problems, as they often require duplicative reviews. Multiple submissions of a single protocol and its associated consent documents to several Research ERBs for review and alterations create redundancy without necessarily enhancing the protection of research subjects.

Many parties, including the Institute of Medicine (IOM), the National Bioethics Advisory Commission (NBAC), and the Department of Health and Human Services (DHHS), note that these duplicative reviews can actually detract from subject protections by diverting time and resources from more effective uses; they have suggested streamlining review through the use of alternative models. Collaborative approaches to ethical review that capture the best of both central and local processes could be more efficient, less costly and less demanding of limited resources, and also be more effective. They may allow for more timely data collection and analysis of adverse events, address the problem of institutional conflict of interest, and offer more options for unaffiliated investigators and patients with rare diseases.

Central review boards have taken on increasing importance in recent years. Reference to a “central IRB” does not necessarily mean that one Research ERB is always the IRB of record; use of the term “cooperative review” may more accurately reflect the emerging approaches discussed in this article. In a survey by the Association of American Medical Colleges (AAMC) of research deans at institutions using a Central IRB (defined as any non-institutional board or cooperative arrangement), 53% agreed that its use shortened time to approval of research protocols. Eighty-four percent were pleased with the Central...