Use of Central IRBs for Multicenter Clinical Trials

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Objectives
1. Identify current perceptions of the barriers to obtaining feedback on proposed solutions to overcome these barriers (see Table).
2. Obtain feedback on proposed solutions
3. Formulate solutions to overcome these barriers
4. Identify standard data elements to facilitate review and reporting across disparate systems.

Background
Maximizing the efficiency of multicenter clinical trials can only be achieved through effective oversight by regulatory agencies. To improve the efficiency of conducting multicenter clinical trials in the United States, the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), and the Department of Health and Human Services (DHHS) support the use of central IRBs.

Methods
We noted barriers from the 33 peer-reviewed articles that we found on the use of central IRBs for multicenter trials in the U.S.

Expert Discussions
We held a series of group and individual discussions with 63 experts, including representatives from institutional, federal, and commercial IRBs, industry sponsors of clinical research, FDA, industry, and regulatory representatives from institutional, federal, and advocacy groups.

Participants
Representatives from institutional, federal, and regulatory representatives from institutional, federal, and advocacy groups.

Results
1. Feasibility of working with multiple outside IRBs, each requiring different forms and/or electronic systems to submit a protocol
   a. Charge an administrative fee for institutional review.
   b. Identify standard data elements to facilitate review and reporting across disparate systems.

Recommendations
To address blurred distinctions between responsibilities for ethics review and other institutional obligations, CTTI recommends that sponsors in a position to require the use of a central IRB (defined as a single IRB of record for all sites) consider the development of guide to support communication and contractual relationships between institutions and a central IRB.

References
CTTI recommends that sponsors in a position to require the use of a central IRB for multisite trial networks should do so in order for relevant stakeholders to gain experience with central IRB review. The resulting experiences may foster greater comfort and trust with the central IRB model.

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