CTTI Recommendations: Use of Central IRBs for Multicenter Clinical Trials

1. CTTI recommends using a central IRB (defined as a single IRB of record for all sites) to improve the quality and efficiency of multicenter clinical trials.

2. To address blurred distinctions between responsibilities for ethics review and other institutional obligations, CTTI recommends that sites and IRBs use a CTTI-developed guide, also known as the Considerations Document, to support communication and contractual relationships between institutions and a central IRB.

3. CTTI recommends that sponsors in a position to require the use of central IRB review 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.

Definition of Central IRB: A single IRB of record for all sites involved in a multicenter protocol. A range of entities may serve as a central IRB (e.g. another institution’s IRB, a federal IRB, an independent IRB).
References


▶ These recommendations are based on results from CTTI’s Central IRB Project.
▶ CTTI’s Executive Committee approved the recommendations.
▶ Released in January 2013