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 multi-center protocol. A range of entities may serve as a central IRB (e.g. another institution's IRB, a federal IRB, an independent IRB).

References

Menikoff J. The paradoxical problem with multiple-IRB review. *N Engl J Med,* 363: 1591–1593.

Abbott D, Califf R, Morrison BW, et al. Cycle time metrics for multisite clinical trials in the US. *Ther Innov Reg Sci*, 00 (2013), pp. 1–9.

US Food and Drug Administration. Guidance for industry: using a centralized IRB review process in multicenter clinical trials. 2006(July 31, 2012).

Menikoff J. Office of Human Research Protections Public Correspondence on Central IRBs. 2010; http://www.hhs.gov/ohrp/policy/Correspondence/mcdeavitt20100430letter.html. Accessed August 6, 2012.

Department of Health and Human Services. Human subjects research protections: enhancing protections for research subjects and reducing burden, delay, and ambiguity for investigators. *Fed Regist.* 2011;76:44512-44531.

Check DK, Weinfurt KP, Dombeck CB, et al. Use of central institutional review boards for multicenter clinical trials in the United States: A review of the literature. *Clinical Trials* 2013;10:560–567.

Flynn KE, Hahn CL, Kramer JM, et al. Using central IRBs for multicenter clinical trials in the United States. *PLoS One* 2013;8(1): e54999.