



**Use of Central IRBs for Multicenter Clinical Trials**  
**Summary of an Expert Meeting held April 25-26, 2012**

Project: Use of Central IRBs for Multicenter Clinical Trials

Clinical Trials Transformation Initiative

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Meeting objectives

The Clinical Trials Transformation Initiative (CTTI) has been conducting a project to summarize known barriers to using central IRBs for multicenter clinical trials and to propose solutions to obviate these barriers. To further explore these solutions, the CTTI working group invited representatives from a broad cross-section of the clinical trial enterprise, including government and industry sponsors of clinical research, academic and non-academic research institutions, commercial IRBs, and patient advocates, to an expert meeting held in Rockville, MD, on April 25-26, 2012. The key objectives of this meeting were to:

- Present research findings from the CTTI project entitled, *Use of Central IRBs for Multicenter Clinical Trials*
- Discuss research findings among experts present at the meeting
- Solicit additional feedback to refine proposed solutions

Overview of CTTI Central IRB project

As multicenter clinical trials have become more common, many have begun to question whether the goal of protecting research participants is enhanced by having each site's local IRB conduct a full review of multicenter protocols. Both the FDA and OHRP have issued statements in support of central IRBs as a means of improving the efficiency of clinical trials. However, local IRBs differ in their willingness to defer to central review. The present research was conducted by the Clinical Trials Transformation Initiative (CTTI) in an effort to solicit current perceptions of barriers to the use of central IRBs and to articulate solutions to obviate these barriers.

The study team began by conducting a review of the literature and holding a series of discussions with experts in the field (n=43) to arrive at an understanding of the barriers to central review. As a result of these activities, an early research finding was the need for clarity in

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defining what is meant by “central IRB.” For purposes of this research, the following definition was adopted: “A properly constituted investigational review board to which sites cede all regulatory responsibility for scientific oversight and integrity of the protocol from initial review to termination of the research, including review of informed consent.” This is distinct from other alternative models of review, such as the facilitated, federated, and consortium models.

We also conducted interviews with stakeholders (n=25) at six different research institutions to obtain feedback on proposed solutions to the identified barriers to central review. The research institutions had various concerns about using an external central IRB. Many of these concerns seemed to be associated with the conflation of the responsibilities of the institution with the ethical review responsibilities of the IRB. Thus, we concluded that there would be value in decoupling these distinct sets of responsibilities to help elucidate how an institution might operate when using an external central IRB.

#### Expert meeting

At the meeting, we discussed detailed strategies and tools for helping research institutions separate institutional responsibilities from those required of the IRB. One such tool was a document created by the project team, which clearly delineates these responsibilities and how they might be assigned to each entity, or, in some cases, both entities. A number of other strategies were also discussed that would allow institutions to gauge their comfort with using centralized review for a particular protocol, including strategies for evaluating the central IRB’s policies and procedures. Recommendations and strategies from this meeting are being compiled for publication and dissemination.