

# ARE YOU READY FOR MANDATED SINGLE IRB REVIEW FOR MULTICENTER CLINICAL TRIALS?

Expert Meeting



MEETING DETAILS | NOV. 14, 2017



## BACKGROUND

Using a single IRB (sIRB) for multisite trials can improve the quality and efficiency of multicenter clinical trials. Since 2010, the Clinical Trials Transformation Initiative (CTTI) has worked to address barriers to the adoption of sIRB for multicenter clinical trials, developing recommendations and resources for the enterprise. In 2014, the National Institutes of Health (NIH) released a draft policy referencing CTTI's work and recommended the use of central IRBs to increase the efficiency of multicenter clinical trials.

Then, in 2016, the NIH issued a final policy requiring the use of a sIRB for multicenter NIH-funded clinical trials effective Jan. 25, 2018. In 2017, the final changes to the Common Rule were announced, including a mandate that U.S. institutions involved in cooperative research in the U.S. (with certain exceptions) use an sIRB, effective Jan. 20, 2020.



## MEETING OBJECTIVES

The purpose of this meeting was to determine further actions that CTTI, the U.S. Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), and NIH can take to ease the transition to mandatory sIRB review for multisite research. Participants—including representatives from academia, government agencies, IRBs, pharmaceutical and device companies, contract research organizations, patient groups, and others—convened to:

- Discuss the upcoming NIH policy and Common Rule changes regarding sIRB review as well as existing FDA Guidance on Centralized IRB Review Process in Multicenter Clinical Trials.
- Identify the remaining gaps in knowledge, guidance, and tools for implementing an sIRB review model.
- Brainstorm potential solutions regarding implementation of the sIRB model for federally funded (e.g., NIH-sponsored) and FDA-regulated drug and device multicenter clinical studies.



## MEETING THEMES

- **Clarity is Needed:** Clearly defined terms are needed to describe which studies will be required to use sIRB.
- **Collaboration is Key:** Early engagement, transparency, and communication among all parties can help mitigate challenges associated with implementing an sIRB model.
- **Opportunity to Learn from Others:** Examples illustrating successful models for sIRB implementation are needed—and the private sector’s experience could be valuable to academic and government research organizations.



## NEXT STEPS

Participants provided recommendations for what CTTI, the FDA, OHRP, and NIH can do to help transition to mandatory sIRB review for multisite research. These recommendations will serve as a starting point for new CTTI projects and/or committees to develop additional resources and strategies.



## ADDITIONAL RESOURCES

- **Meeting materials**, including agenda, participant list, and presentations
- Read more about CTTI’s **Single IRB Program**
- For more information, please contact Sara Calvert at [sara.calvert@duke.edu](mailto:sara.calvert@duke.edu)



## ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations, CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Learn more about CTTI at [www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org).



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