



# Are You Ready for Mandated Single IRB Review for Multicenter Clinical Trials?

**Agenda of the Workshop held Nov. 14, 2017**

DoubleTree by Hilton Hotel Silver Spring  
8727 Colesville Rd.  
Silver Spring, MD 20910

**CTTI MISSION:** To identify and drive adoption of practices that will increase the quality and efficiency of clinical trials

## **MEETING OBJECTIVES:**

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

## TUESDAY, NOV. 14, 2017

### 9:00 a.m. Welcoming Remarks

9:00 a.m. Introduction to the Clinical Trials Transformation Initiative and Central IRB Projects  
*Sara Calvert, Clinical Trials Transformation Initiative (CTTI)*

### 9:15 a.m. Session I: Review Single IRB Policies, Rules and Guidance

*Session I Facilitator: Bridget Foltz, Food and Drug Administration, GCP*

*Session I Objective:*

- ▶ Review upcoming NIH policy and Common Rule changes regarding single IRB review as well as existing FDA Guidance on Centralized IRB Review Process in Multicenter Clinical Trials.

9:15 a.m. NIH Single IRB Policy  
*Petrice Brown-Longenecker, National Institutes of Health*

9:30 a.m. Review of Changes to the Common Rule Regarding Use of Single IRB  
*Yvonne Lau, OHRP*

9:45 a.m. Review of FDA Guidance on Centralized IRB Review Process in Multicenter Clinical Trials  
*Bridget Foltz, FDA*

10:00 a.m. Questions and Group Discussion

### 10:30 a.m. Session II: Discuss Available Resources for Implementation of Single IRB for Multicenter Clinical Trials

*Session II Facilitator: Cynthia Hahn, Integrated Research Strategy*

*Session II Objectives:*

- ▶ Review available resources for implementation of single IRB model for multicenter clinical trials.
- ▶ Discuss successful practices for implementation of a single IRB model.

10:30 a.m. Review of Resources from CTTI Central IRB Projects  
*Cynthia Hahn, Integrated Research Strategy*

10:45 a.m. SMART IRB Platform Overview  
*Petra Kaufmann, National Center for Advancing Translational Sciences, NIH*

10:55 a.m. SMART IRB Exchange and the NIH Trial Innovation Network  
*Emily Serdoz, Vanderbilt University Medical Center*

11:10 a.m. Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) Proposed Single IRB Review Standard  
*Robert Hood, AAHRPP*

11:25 a.m. Group Discussion of Successful Practices

## TUESDAY, NOV. 14, 2017 (Cont.)

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### 12:45 p.m. Session III: Breakout Sessions

12:45 p.m. *Breakout Session Instructions: Sara Calvert, CTTI*

*Session III Objectives:*

- ▶ Discuss the remaining gaps in knowledge, guidance and tools for implementing a single IRB review model.
- ▶ Propose solutions regarding implementation of single IRB model for multicenter clinical trials whether federally funded (e.g., NIH-sponsored) or FDA-regulated drug and device studies.

Regulatory Breakout Group

*Facilitator: Amy Corneli, CTTI*

Operational Breakout Group

*Facilitator: Brian Perry, CTTI*

### 2:45 p.m. Session IV: Summary of Challenges, Discuss the Path Forward

2:45 p.m. *Session IV Facilitator: Amy Corneli*

*Session IV Objectives:*

- ▶ Share highlights from breakout groups.
- ▶ What can FDA, OHRP, NIH, and/or CTTI do to help transition to mandatory single IRB review for multisite research?
- ▶ Discuss next steps.

3:30 p.m. **Adjourn and Departures**