CTTI RECOMMENDATIONS: ADVANCING THE USE OF CENTRAL IRBS FOR MULTICENTER CLINICAL TRIALS

CTTI issued recommendations and published a guide in January 2013 to address barriers to the adoption of a central IRB model for multicenter clinical trials. CTTI defines a Central IRB as 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). A follow-on project, Advancing the Use of Central IRBs for Multicenter Clinical Trials, was launched in early 2013 to address remaining barriers and encourage implementation of the recommendations.

1. CTTI recommends use of the CTTI-developed Evaluation Checklists:
   - for institutions to determine their readiness to use a Central IRB (federal, academic, or independent IRB) for multicenter clinical trials,
   - for institutions/sponsors when selecting a particular IRB to serve as the single IRB of record, and
   - for Central IRBs when deciding whether to work with a specific institution during a multicenter clinical trial.

2. To address administrative and legal concerns and to reduce time when first executing a reliance (authorization) agreement, CTTI recommends that institutions and IRBs adopt or begin negotiations with the CTTI-developed IRB Authorization Agreement Template.

3. To address local context concerns, CTTI recommends that IRBs and institutions follow the Secretary's Advisory Committee on Human Research Protections (SACHRP) Recommendations on Consideration of Local Context with Respect to Increasing Use of Single IRB Review (January 2013).

4. CTTI recommends additional research be conducted to further define quality in IRB review.

5. CTTI recommends research be conducted to develop data and technology standards across electronic IRB application systems to facilitate communication and efficacious and transparent review.

- *These recommendations are based on results from CTTI's Advancing the Use of Central IRBs for Multicenter Clinical Trials Project.*
- *CTTI's Executive Committee approved the recommendations.*
- *Released April 2015*