Landscape of the Use of Central Institutional Review Boards for Multicenter Clinical Trials

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- Presenter is employed by Celgene Corporation
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A “central IRB” can be a non-commercial IRB, but used as a single IRB of record to which sites cede all regulatory responsibilities / scientific oversight and integrity of the protocol from initial review to termination, including ICF.
**Historical Timeline**

- **First Independent IRB in US**
- **National Research Act**
- **OHRP Guidance: Knowledge of Local Research Context**
- **Common Rule**
- **FDA Regulations**
- **OPPR(OHRP) Single Project Assurance**
- **AAHRPP Founded**
- **FDA Guidance: IRBS Registration**
- **VA CIRB**
- **FDA Guidance: Use of Central IRBS**
- **Conf on Alternative IRB Options (NIH, OHRP, AAMC, ASCO, VA)**
- **NEJM Menikoff Editorial**
- **NEURONEXT Awarded**
- **CTTI Use of CIRB Recommendations**
- **NINDS Strokenet Awarded**
- **Several NIH RFAs with CIRB**
- **OIG Rpts: Independent IRBS & IRBS Time for Change**
- **Common Rule**
- **ANPRM: Revision to Common Rule**
- **NCI CIRB 881 Enrolled Institutions/Affiliates**
- **NCI CIRB 881 Institution/Affiliates**
CTTI Project: Use of Central IRBs for Multicenter Clinical Trials

Goal
Identify solutions to address barriers to the adoption of central IRBs for multicenter clinical trials

Objectives were to:
- Solicit current perceptions of barriers
- Develop a strategy to address the identified barriers
- Assess reactions to proposed solutions to remove these barriers
Methods

- Literature Review
- Expert Advisory Panel
  - Institutional, federal, and commercial IRBs, industry, and regulatory agencies
- Semi-structured Interviews
  - Stakeholders at six research institutions that did not typically use central IRBs
- Expert Meeting
  - FDA, OHRP, federal and industry sponsors, independent IRBs, research institutions, and patient advocates
Results: Need to clarify terms

- **Central IRB = Single IRB-of-record for a given protocol**
  - To which sites cede all regulatory responsibility for scientific oversight and integrity of the protocol from initial review to termination of the research including informed consent
  - A range of entities may serve as a central IRB
    - e.g., independent IRBs, federal IRBs, another institution’s IRB
  - Implies that an institution not choosing to use the single IRB-of-record would not participate in that protocol
Results: Common themes

- Concerns seemed to be associated with conflation of the responsibilities of the institution with the ethical review responsibilities of the IRB
  - Developed “considerations document”

- Remaining discomfort due to lack of experience using centralized review
Recommendation #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.

*CTTI's 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).
Recommendation #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* to support communication and contractual relationships between institutions and a central IRB.

*Considerations Document
Recommendation #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.
CTTI Central IRB Advancement Project

- Follow-on to original project
- To assess and propose solutions for remaining areas of concern for using single IRBs of record for multicenter clinical trials
- To advance the use of central IRBs for multicenter clinical trials

Deliverables
- Webinar Series
- Expert Meeting
- IAA Template
- Publication and public posting of results
Meeting Objectives

- Discuss practices, implementation strategies, and solicit additional suggestions for increasing the use of central IRBs for multicenter clinical trials
- Present findings from the CTTI Central IRB Advancement project’s collection of IRB authorization agreements and standard operating procedures
- Obtain additional feedback to refine proposed IAA template
Ensuring Human Research Protection

- Ethics
- Values
- FDA
- Approved
- Safeguards
- Preserving Public Trust
- Protection of Human Research Subjects
- Conflict of Interest
Thank you.