CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Use of Central IRBs for Multicenter Clinical Trials Evaluation Checklist

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The purpose of this document is to assist organizations with adoption of a central IRB (a single IRB of record for all sites) model for multicenter clinical trials. Included are suggestions for each of the following:

- Institutional Self-Evaluation (Adoption readiness)
- Institution/Sponsor Evaluation of a Central IRB
- Central IRB Evaluation of an Institution

The three checklists are part of one document to allow all stakeholders to gain insight from each, even if they are not the target audience for that list.

Are you CONSIDERING adopting a Central IRB model for multicenter clinical trial protocols?

▶ Institutional Self-Evaluation

General considerations for institutions deciding whether to adopt the Central IRB model

❑ **Assess your organizational culture**

_____ Determine the level of investigator and institutional buy-in

_____ Educate the institution about institutional responsibilities versus IRB responsibilities (See CTTI Considerations Document)

_____ Evaluate concerns about potential loss of control by outsourcing ethical review

_____ Consider impact of adopting a central IRB model on the institution's Human Research Protection Program (HRPP) goals and business goals for clinical research. Speak to similar institutions/entities that have used a central IRB for multicenter clinical trials.

❑ **Assess governance of your HRPP and determine who within the institution will provide institutional approval for a study to proceed regardless of IRB of record**

❑ **Review your HRPP policies / procedures and other institutional governing agreements**

_____ Ensure you have institutional policies that apply regardless of IRB utilized

_____ Define processes for the investigator, institution, institutional HRPP, and central IRB

- Institutions may need to review and revise the terms of their medical staff by laws or other governing documents if they reference requirements for use of an institutional IRB or reporting of IRB decisions
- Institutions may need to review and/or revise the contractual terms or obligations of their physicians if their employment agreements require use of the institutional IRB.

❑ **Develop training programs for investigators and HRPP staff that apply regardless of IRB utilized**

❑ **Determine impact on electronic systems used in HRPP data collection**

❑ **Consider the type of research being conducted**

_____ Level of risk

_____ Funding environment

_____ Number of sites involved

❑ **Conduct a financial analysis**

_____ Evaluate costs – both of using a central IRB and missed research opportunities if not using a central IRB

_____ Establish fee structure for conducting institutional tasks

_____ Assess scalability of the central IRB model

▶ Institution / Sponsor Evaluation of a Central IRB

General considerations for institutions and sponsors when selecting a particular Central IRB

❑ Consider IRB's certifications and accreditation

❑ Investigate compliance history of the IRB

❑ Review qualifications of board members, including therapeutic expertise

❑ Request references; review organization's history of working with institutions and/or sponsors

❑ Evaluate IRB's ability to step seamlessly into the process
(including state laws and local considerations)

❑ Determine scope and associated costs of services provided

❑ Obtain description of support services provided
_____ For the institution to manage the change to a central IRB
_____ For investigators, start up and ongoing, to work with the central IRB
_____ Establish communication process between institution, investigator, and IRB

❑ Assess operational processes (frequency of board meetings, document management, capacity, turn around time, QA processes: internal and external)

❑ Inquire about technology used by Central IRB and compatibility with existing systems/programs

▶ Central IRB Evaluation of an Institution

General considerations for Central IRBs when deciding whether to work with a specific institution

- ❑ Investigate compliance history of the institution
- ❑ Consider the goals of the institution – what are the drivers?
- ❑ Determine relevant laws, local regulations, institutional norms and values, requirements
- ❑ Specify point(s) of contact at the institution and lines of communication
- ❑ Establish level of involvement in unanticipated problems, and other problems
- ❑ Review institution's experience working with outside IRBs
- ❑ Gauge institution's expectations regarding central IRB's performance and metrics
- ❑ Decide desired scope of agreement and specific studies (one study, all studies, or certain subset of studies)
- ❑ Identify process for confirming consistency between protocol, informed consent, and clinical trial agreement