IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

A **freely available** web-based portal that supports **single IRB (sIRB) documentation** and **communication** for multi-center clinical trials, such as:

Basic Reliance Documentation

- **sIRB agreement completion**
- **Study-specific reliance/cede decisions**

Advanced Reliance Documentation

- **Study-specific local considerations from site HRPPs/IRBs**
- **Site differences in study conduct and investigator attestations**
- **sIRB approval documents for each site**

Single / Reviewing IRBs
use IREx to centrally capture information from site HRPPs/IRBs and study teams.

Lead Study Teams & Coordinating Centers
use IREx to track site progress towards sIRB review and approval.

Participating Site HRPPs/IRBs
use IREx to document reliance and local reviews/ considerations for the sIRB.

Participating Site Study Teams
use IREx to document information for the sIRB and retrieve sIRB approvals.

Central Portal: *Standardize the reliance process across sIRBs*

Using IREx promotes a standardized single IRB review process by offering a central portal to capture critical reliance documentation and information, support sIRB coordination, and facilitate communication between the sIRB, study teams, and relying HRPPs for a study's life cycle.

Local Considerations: *Harmonize sIRB data collection*

The Institutional Profile (IP)

All sites complete an IP upon joining IREx. The IP captures (1) general FWA/IRB information; (2) overarching local and state laws/policies affecting all research; (3) processes and requirements *when relying on an sIRB*; and (4) preferences for handling the flexible elements of reliance when *serving as the sIRB* (e.g., SOPs, external reporting, and auditing). **The IP is completed once and can be updated as the information changes**.

Study-specific Local Considerations

In addition to the IP, on a **study-by-study basis** participating sites must document the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including ancillary reviews, that would affect the conduct or approval of the study at their institution.

Metrics: *Systematize the evaluation of the sIRB process*

IREx captures time to approval metrics for the Lead and Relying Sites. Importantly, the time to approval starts far before a site is ready for sIRB review and approval. Thus, IREx facilitates the full time-to-approval metric starting with when sites are contacted to begin the reliance process through the time they are reviewed by the sIRB. This time includes when study teams submitted to their local institution for review and local review dates, as well as distinguishes between time in the IRB and time with the study team.

Visit our website: https://IRBExchange.org | Contact us: admin@IRBExchange.org