Use of Central IRBs for Multicenter Clinical Trials

BARRIERS & SOLUTIONS

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Approach

Update barrier list
Propose solutions to remove barriers
Solicit reactions to proposed solutions from diverse stakeholders
Develop recommendations
Update Barriers

Literature review

Expert Advisory Panel
Barriers to Central Review

Review quality *(Local concerns)*

Regulatory liability

Legal liability

Negative public relations

Loss of income from fees

Too many different forms
Inconsistent use of term
“Central IRB”
Current Practices

Independent IRBs

Federal IRBs

Consultants
An independent IRB is not the same as a central IRB
Federated Model

Sites in a network agree on reciprocal acceptance of one another’s IRB review and approval
Consortium Model

Sites agree to a robust centralized review process but do not cede review responsibility to an external body.
Facilitated Model

The protocol is reviewed by the central IRB, then handed down to the institutional IRBs to conduct what is essentially an expedited review.
Single IRB of Record

Sites cede all regulatory responsibility for scientific oversight and integrity of the protocol from initial review to termination of the research, including review of informed consent, to the central IRB.
Sponsors do not mandate use of a single IRB
still no solutions...
Designate only one IRB of record
Regulatory liability falls on the IRB
Institutions would review for compliance with other regulatory requirements
Public Comments

IRB Forum

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Generating Solutions

Accumulated knowledge
Additions to project team
Interviews with expert advisors
Proposed Solutions
Local Context

How much of a problem is this for the protocol?

Institution can add to informed consent

Institution can limit investigator involvement
Administrative

Standardize forms
Financial

Institutional administration fee

Cover fixed IRB costs in another way
Legal & Regulatory

Clarification of OHRP policy to take action against IRB-of-record and not institution for noncompliance with regulations

Define roles of institution and IRB-of-record