

The Value of a Central Institutional Review Board for Multi-Centered Studies Using the Virtual Pooled Registry

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Current IRB Processes for Registry Linkage Studies

- ▶ Multiple reviews of the same protocol by individual IRBs (dueling IRBs).
- ▶ Inefficiencies leading to significant costs in terms of resources, staff time and elapsed time for the registry and the researcher.
- ▶ Inconsistencies among multiple IRB requirements can affect scientific and operational processes.
- ▶ Delays in the initiation and completion of cancer research.

The Common Rule

- ▶ Responsible conduct of research in the context of
 - ▶ Scientific integrity and
 - ▶ Ethical obligations toward research subjects.
- ▶ Three fundamental ethical principles:
 - ▶ Respect for persons taking part in research
 - ▶ Protecting them from risks of research
 - ▶ Ensuring a fair distribution of costs and benefits to research participants.




Proposed Changes to “Common Rule” Require CIRB Use

- ▶ Proposed changes to the Common Rule, will require reliance on CIRBs for U.S. institutions engaged in cooperative research.
- ▶ Goals are to
 - ▶ Enhance and streamline the review process
 - ▶ Reduce inconsistencies
 - ▶ Adjust oversight to match level of risk
 - ▶ Without compromising ethical principles and protections.



What is a Central Institutional Review Board?

- ▶ A CIRB is an independent review board designed to reduce duplication of effort and increase efficiency and consistency by serving as the single IRB of record for multi-center studies.
- ▶ Members of a CIRB are multidisciplinary yet have experience reviewing specific types of studies.
- ▶ When agreeing to work with a CIRB, local IRBS are no longer responsible for conducting study reviews as they agree to accept decisions of the CIRB.



A CIRB promotes and accelerates collaborative research.

- ▶ A CIRB establishes
 - ▶ Common language and regulatory interpretation.
 - ▶ Common processes and consistent approach.
 - ▶ Common standard operating procedures.

Current Examples of CIRB Use

- ▶ **Cancer Research Network (CRN) Virtual Data Warehouse (VDW).**
 - ▶ Network of 15 integrated health organizations contribute data to the VDW and successfully use a CIRB.
 - ▶ Issues associated with the Cancer Research Network VDW are similar to those of the VPR.
- ▶ **NCI CIRBs**
 - ▶ Adult CIRB – Late Phase clinical trials (established 2001).
 - ▶ Adult CIRB – Early Phase clinical trials (established 2013).
 - ▶ Pediatric CIRB – Pilot, Phase 2 & Phase 3 pediatric clinical trials (established 2004).
 - ▶ Cancer Prevention and Control CIRB – Prevention & control clinical trials (established 2015).
- ▶ **Veterans Administration CIRB**
 - ▶ Requires the use of the VA CIRB as a condition for participating in a select group of studies.



Primary Risks Associated with Linkage Studies

- ▶ Primary risks to human subjects associated with linkage studies are specific to a narrow set of concerns:
 - ▶ Privacy
 - ▶ Confidentiality



Benefits of a CIRB for VPR Linkage Studies

- ▶ A CIRB would increase the value of the VPR and promote VPR linkages by
 - ▶ Reducing inefficiencies and duplication of effort for both the registries and the researchers
 - ▶ Reducing inconsistencies related to scientific and operational processes
 - ▶ Reducing delays in the initiation and completion of cancer research
 - ▶ Offering expertise specific to risks related to linkage studies (privacy and confidentiality)

One Application and One Review per Study

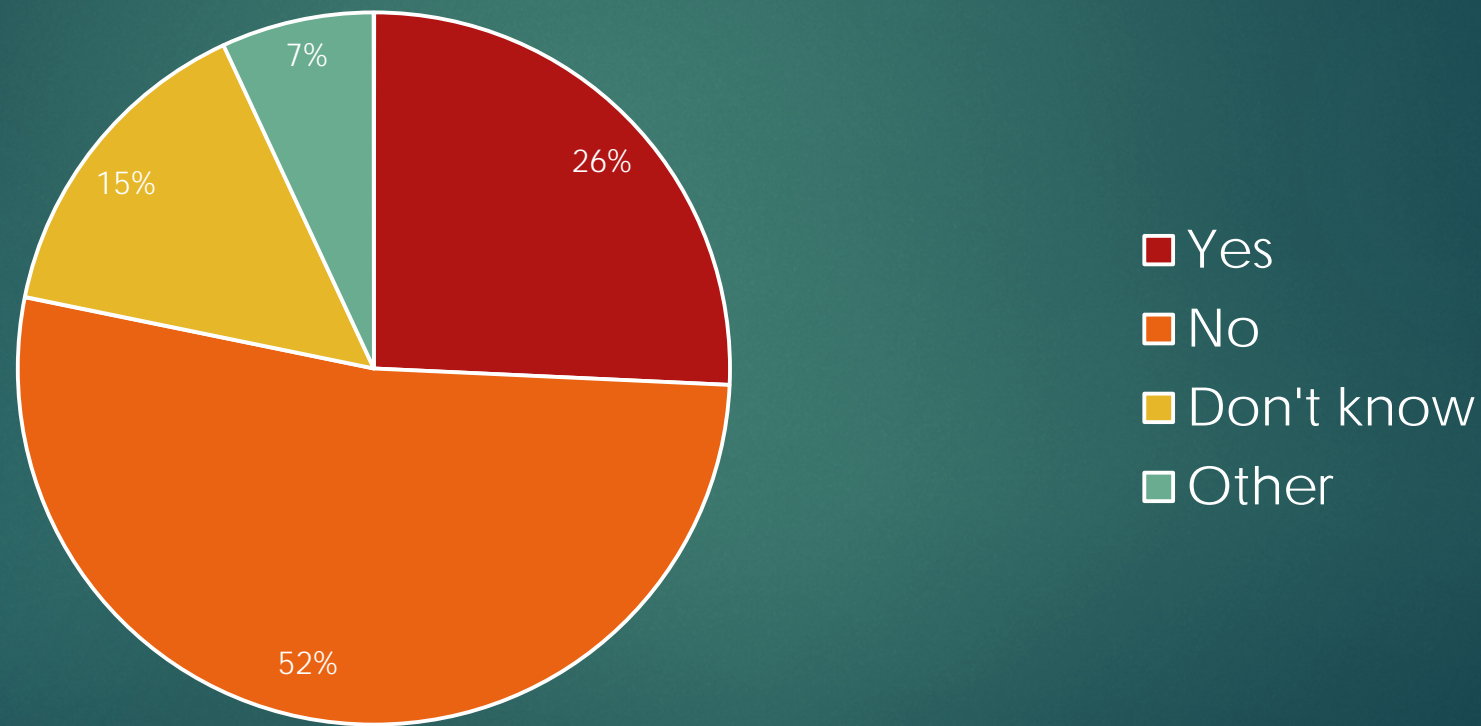
With a CIRB process dedicated to the VPR,
one application and one review per study
would save years of work and millions of dollars.



NAACCR Survey December 2015.

55 of 60 registries responded

Has your registry and/or institution ever accepted a central IRB approval for a research project?





How do we move toward the use of a CIRB for VPR linkage studies?

The VPR is working to develop a CIRB for VPR linkage studies.

We are in the process of moving toward the acceptance and use of both the VPR and a CIRB dedicated to the VPR.