Customizing eIRB Systems to Review Multisite Studies Using a Single IRB Model

Introduction

The eIRB Dilemma for Single IRB

Need for a New Framework

Lessons Learned

Our Resources

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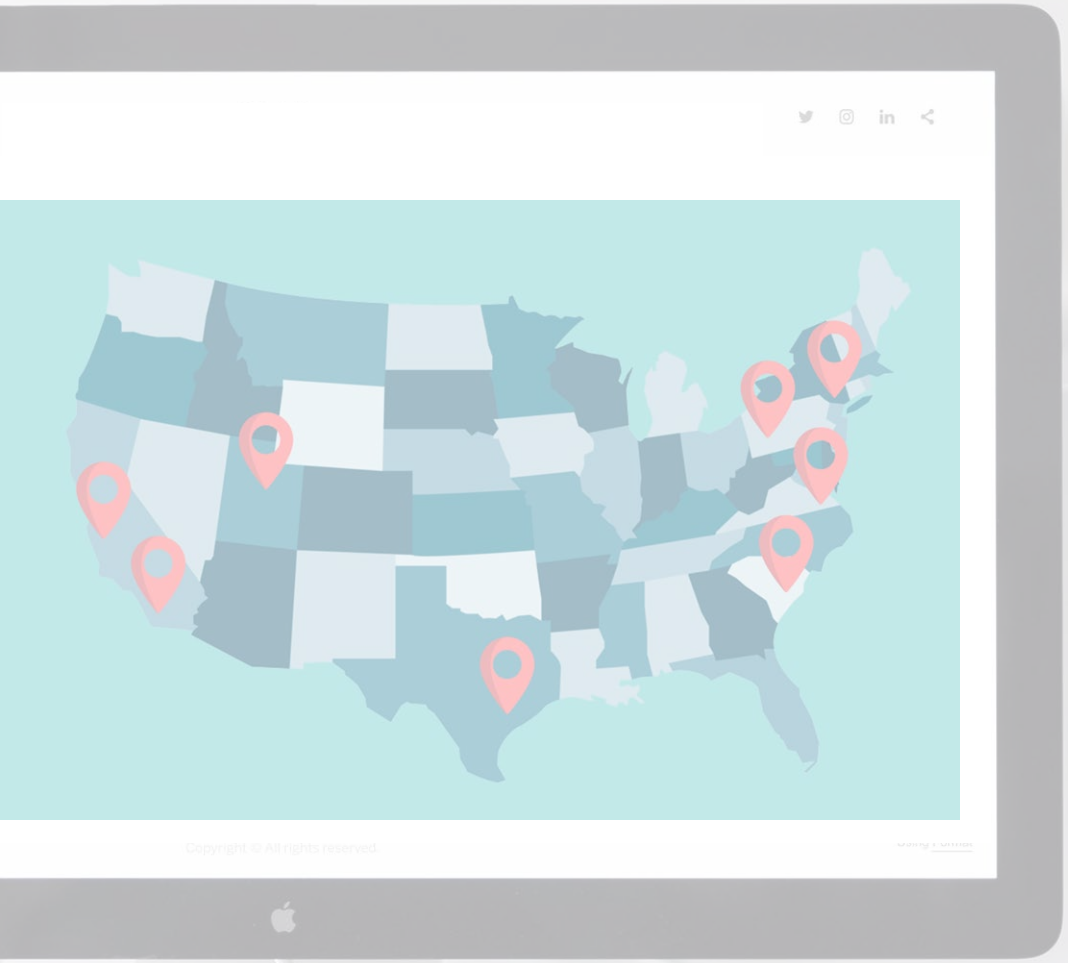


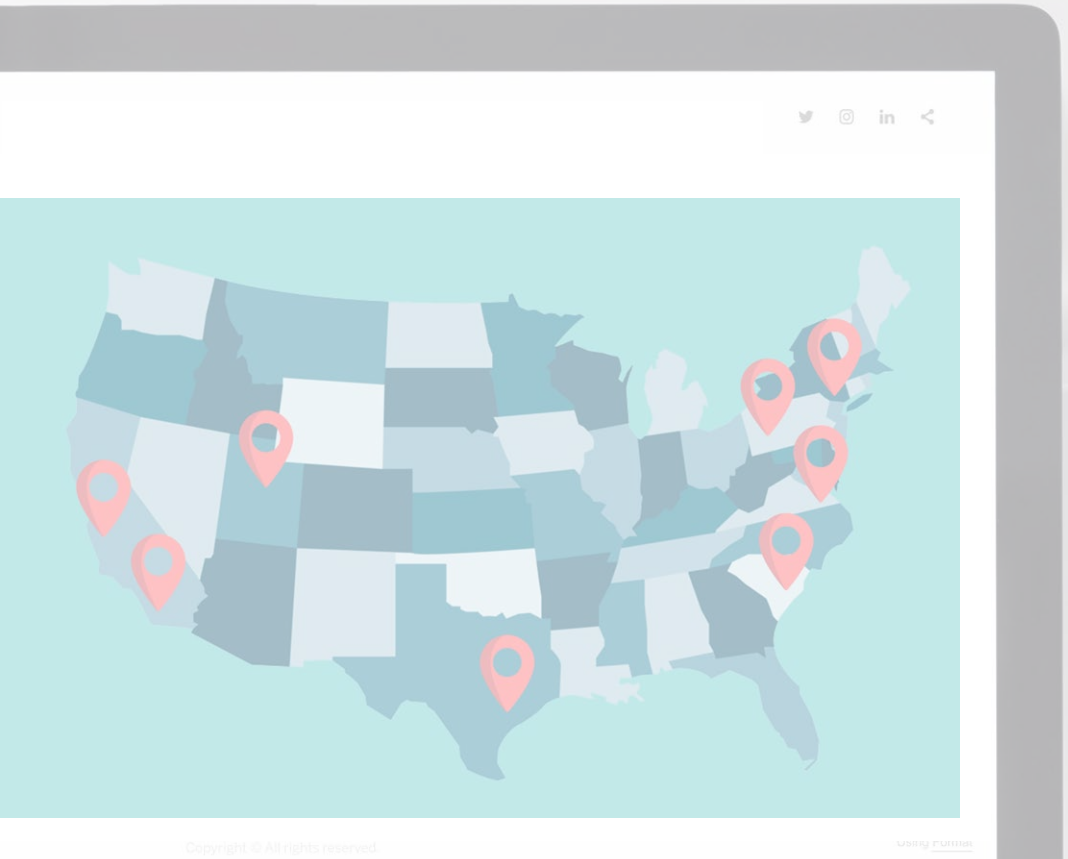
The Dilemma

Within eIRB systems, it can be difficult to manage the activities of multiple sites.

Many eIRB applications are set up to collect site-level information in the study-level application.

By doing this, an IRB reviews the study-level and site-level information together.

This can cause review delays if all levels of information are not ready at the same time.



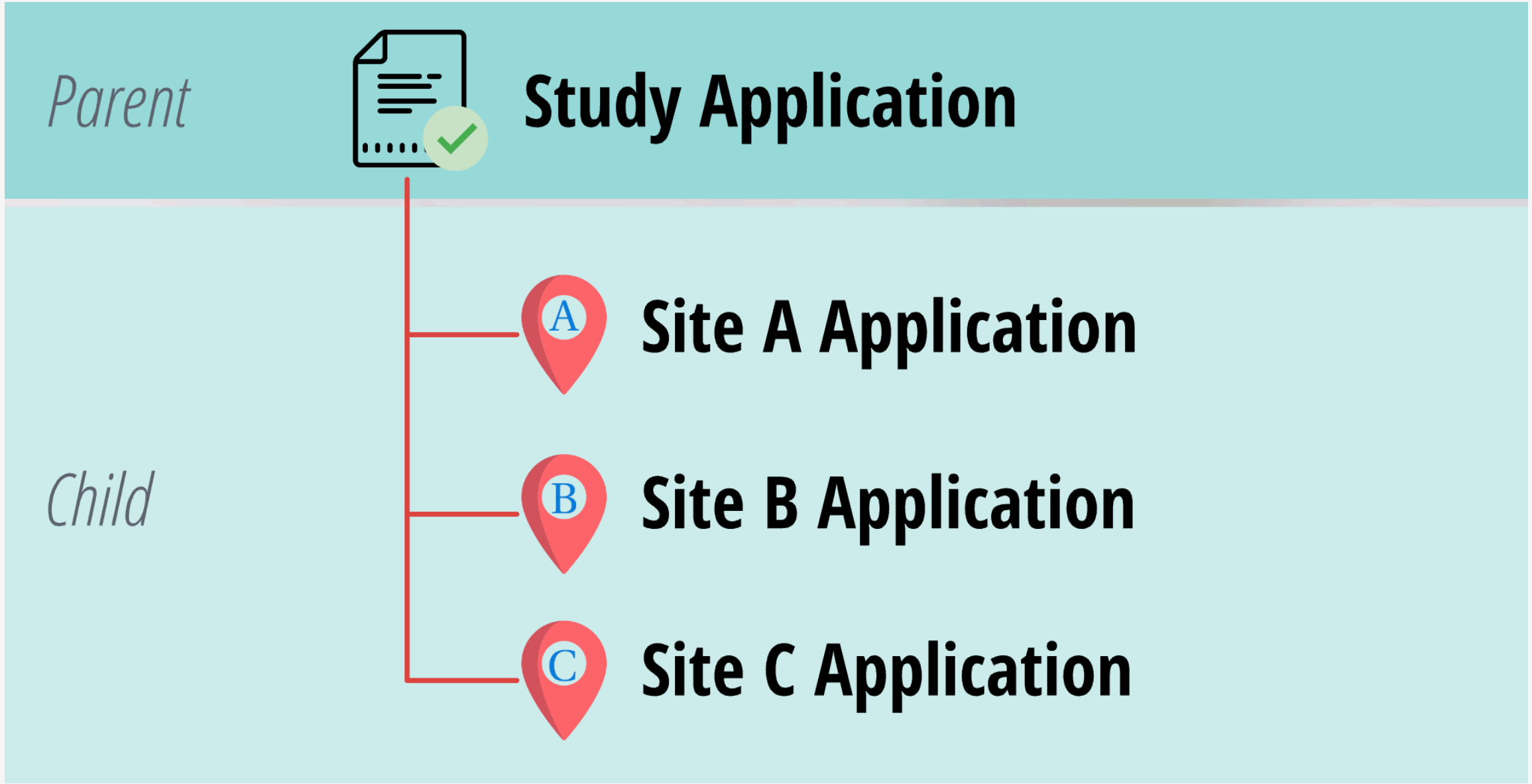
New Framework

We have found it to be most efficient to collect and review the research protocol and study-level documents separately from the site-level information and documents.

To maximize flexibility, study-level information and site-level information can be collected either in tandem, or sequentially, though the review process for each remain separated.

- The framework was implemented using the Huron RX version of the Click Portal eIRB system.
- **The framework can be used to enhance any modifiable eIRB system.**

The Parent-Child Site Model



Subdividing the Information in the Parent & Child Applications

Key Considerations

- When to collect study-level data, site-level data, or both
- Child sites have read-only access to parent application
- Child sites can only view their documents and those that are study-wide
- Child sites can only amend their site-specific documents

User Roles & Organization of Key Personnel

Key Considerations

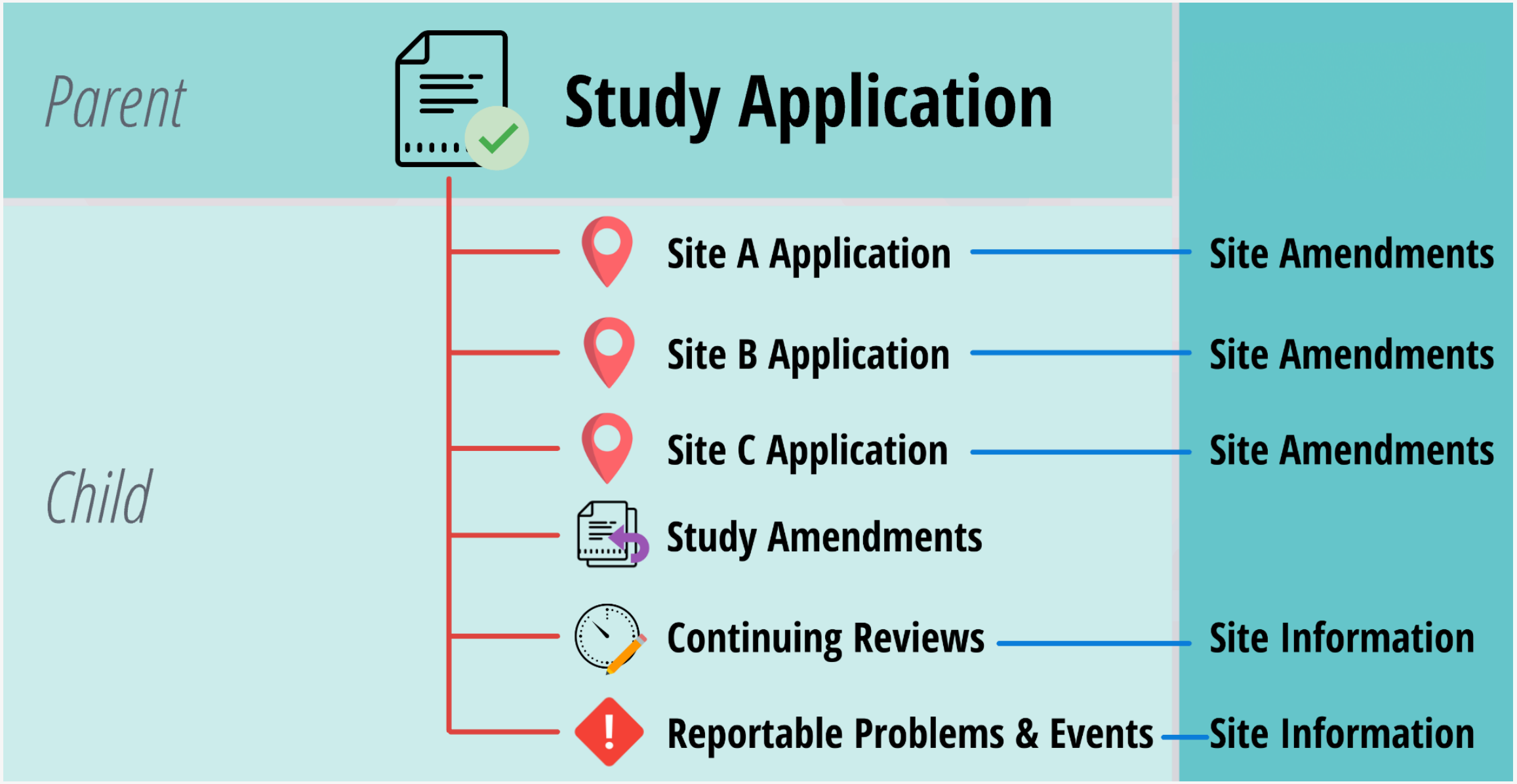
- Organize personnel by site
- Designating levels of access and activity performance based on user role
- Flexibility for compliance with different reliance agreements, including the SMART IRB Master Reliance Agreement
- Options for providing access to external users

sIRB Review for Parent & Child Applications

Key Considerations

- Parent study approved first
- Flexibility for compliance with different reliance agreements, including the SMART IRB Master Reliance Agreement
- Flexibility for review timing; child sites approved as non-substantive changes to the parent
- Checklists for study and site components

Ongoing Review Model



Key Considerations of the Ongoing Review Model

Key Considerations

- Level of independence of the child applications – site ability to submit its own ongoing review information
- Collating child information at the parent-level to get overall view of study
- Sites can be approved with parent or after parent, but not before
- Expiration date assigned at parent level

Impact on Facilitating sIRB Review

Key Considerations

- Streamlines the organization of parent and child documents
- Allows for the sIRB to make determinations on both a site and study-wide level
- Works within an existing workflow with all typical IRB functions intact
- Allows each site to get a site-specific approval letter

MUSC Experience To-Date

25 — Number of sites approved in the first study to use the model.

17 — Study-wide amendments submitted and approved.

74 — Relying site approvals.

370 — Reportable events received and processed.

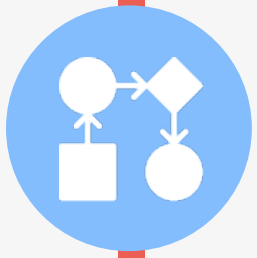
36 — Continuing reviews submitted and approved (for parent and child applications).

sIRB Challenges

Even with a streamlined electronic management system, sIRB review takes a great deal of human hours.

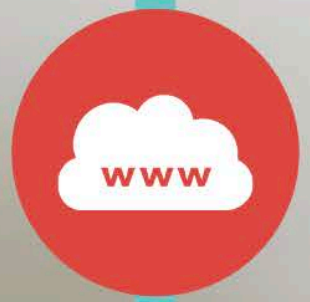
Relying sites that are slow to submit required sIRB documents will still be slow to initiate study.

Lead investigators need sufficient staff to manage document submission and communicate with relying sites.

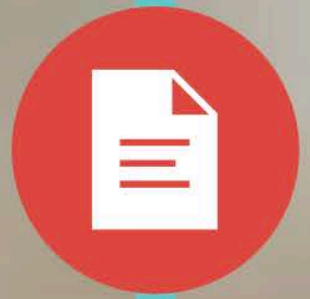


Coordinating centers would be helpful in ensuring a protocol is written for multisite implementation and providing site monitoring and training.

Our Resources



Website



Papers

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