
Children's National
Implementation of NIH sIRB Policy at Children's National Medical Center
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Overview

- Overview of NIH sIRB policy
- Current CNMC portfolio as sIRB of record
- Implementation of NIH sIRB policy
- Responsibilities of lead PI and study team
- Responsibilities of site PI
- Next steps for PIs planning multisite studies subject to NIH sIRB Policy

Purpose: "This policy is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants."

Multi-site study terms and definitions

- ***Single IRB (sIRB):*** A single IRB of record for a multi-site research study
- ***Overall PI:*** The lead multi-site principal investigator with ultimate responsibility for the conduct and integrity of research (generally, the initiating principal investigator or funding principal investigator, as applicable).
- ***Site investigator:*** An investigator(s) responsible for the conduct of the research at his/her participating institution
- ***Reviewing Site:*** Institution maintaining IRB of record.
- ***Relying Site*:** Institution ceding human subjects protections review to sIRB
- ***SMART IRB:*** NCATS funded platform to facilitate conduct of multisite research, relationships, develop standardize d reliance agreements, forms and processes

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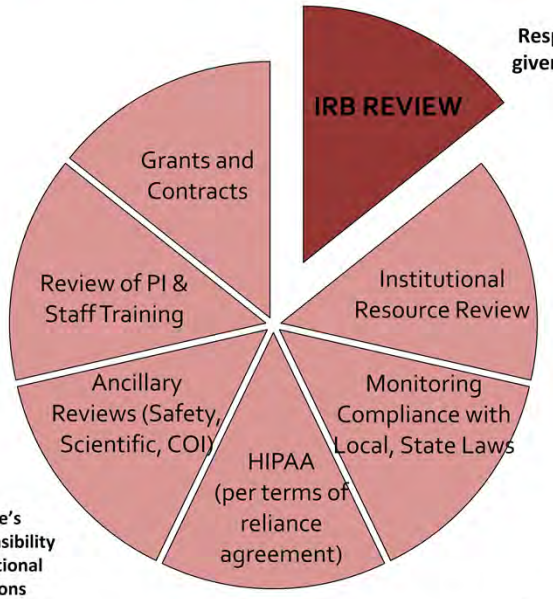
There are two key roles for PIs in multi-site research. Each has specific requirements and responsibilities during grant preparation, study set up, and conduct of the study.

Single IRB Review is not Single Institutional Review



Responsibilities given to the sIRB

Each participating site's institution retains responsibility for ancillary and institutional reviews and verifications

*Slide adapted with permission from Megan K. Singleton (JHU IRB)

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IRB Responsibilities vs Institutional Responsibilities

Reviewing IRB Responsibilities

- Maintain IRB membership consistent with regulatory requirements
- Make IRB findings and determinations
- Notify investigators of findings/determinations
- Ensure study is compliant with federal IRB requirements
- Review of local considerations provided by the relying organization
- Reporting regulatory determinations to federal oversight agencies
- Managing IRB-directed audits

Relying Institution Responsibilities

- Conduct all required institutional reviews
- Identify and communicate to the Reviewing IRB any local considerations
- Researcher education & training
- Routine Monitoring/Compliance oversight for research conducted at the organization
- Identification and analysis of conflicts of interest

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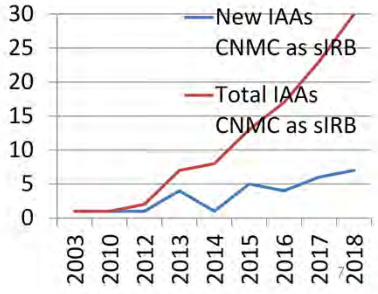
Current CNMC sIRB Activities

- We currently serve as the sIRB of record for 6 multisite studies across two networks (predate NIH policy)

RARE CLINICAL DISEASES RESEARCH NETWORK
Initiative of the National Center for Advancing Translational Sciences (NCATS)

CHILDREN'S HOSPITAL ASSOCIATION
CARE AWARD

- Continue to serve as IRB of record for collaborations (not subject to NIH policy) with regional partners and other institutions on a protocol by protocol basis (i.e. current agreements with GWU, Inova, PSV, NIH Clinical Center, other collaborating US institutions)



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CNMC Implementation of NIH sIRB Policy

During the first two years of the NIH Policy, we have agreed to serve as sIRB of record for one additional study subject to policy. Otherwise, will serve as relying institution for studies subject to NIH policy . Approach allows for:

- Piloting **costing model** per evolving NIH guidance
  - administrative support for site specific sIRB related activities is required, should be budgeted (when relying and reviewing)
  - sIRB activities associated with the review of site-specific considerations for each participating site reimbursed as direct costs and should be included in budget
- Developing **template language** for grant submissions when we are relying site and reviewing site
- Developing **letter of support templates** (relying and reviewing institution)
- Revising **SOPs**
- **Monitoring emergence of best practices**

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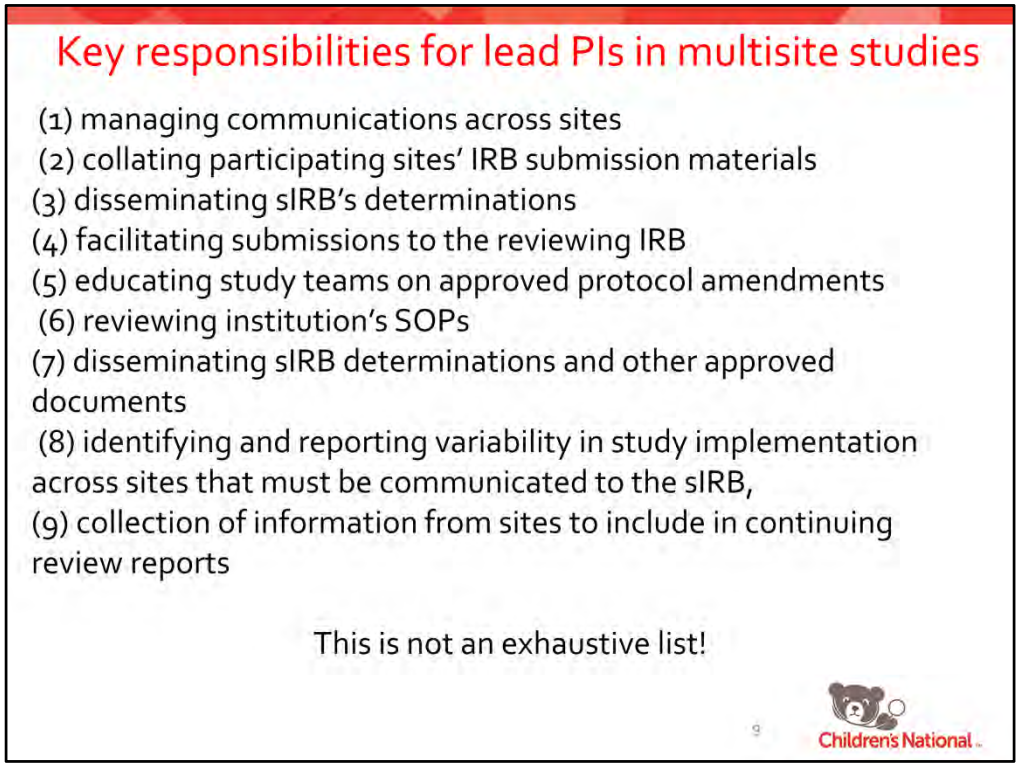

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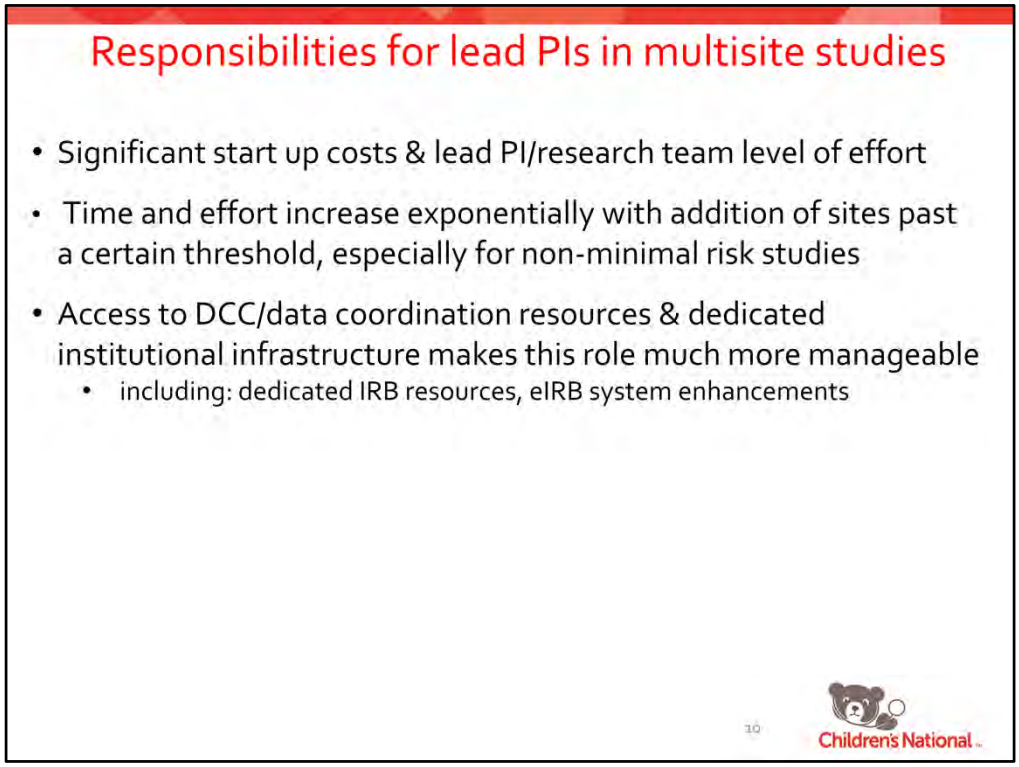

- **Not as simple as the NIH sIRB policy makes it seem**

Responsibilities of site PIs in multisite studies

When PI's institution is the relying institution:

- Understand policies, systems and timelines of reviewing IRB
- Meet local institutional policies and requirements
- Obtain needed local institutional ancillary reviews

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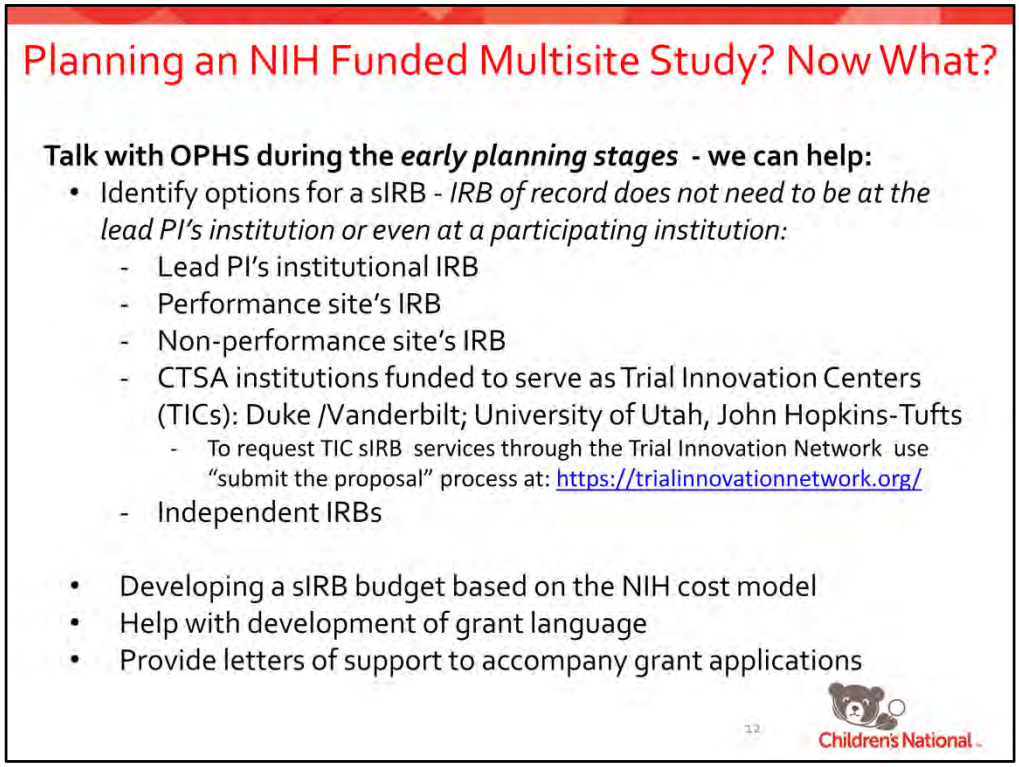

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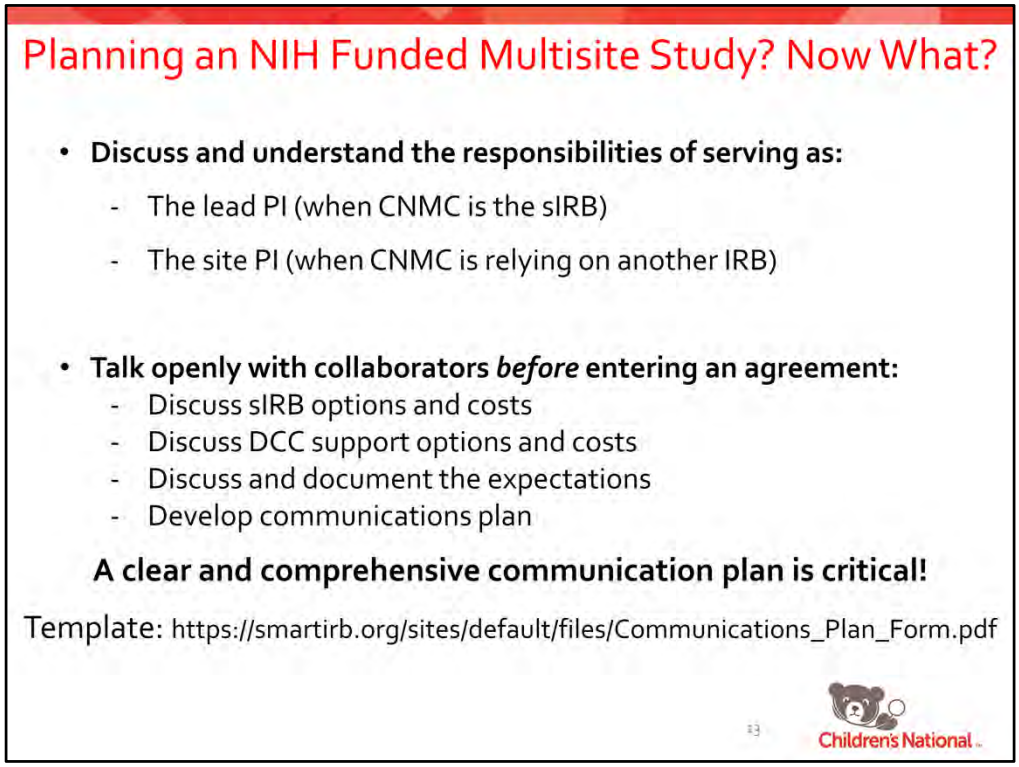

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NIH sIRB Policy & Implementation Resources

URL:
https://osp.od.nih.gov/clinical-research/irb-review/

- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
- Federal Register Notice on the Final NIH sIRB policy
- Federal Register Notice on sIRB Effective Date Extension
- NIH Guide Notice on the Final sIRB policy
- NIH Guide Notice on sIRB Effective Date Extension
- NIH Director's Statement on the NIH sIRB policy
- OSP-OER Blog on the sIRB policy
- NCATS SMART IRB Reliance Platform
- Frequently Asked Questions about the Implementation of the sIRB policy
- NIH Guide Notice on Scenarios Illustrating the Use of Direct and Indirect Costs for Single IRB Review Under the sIRB Policy
- NIH Policy on the Use of a Single IRB for Multi-Site Research FAQs on Costs
- Request for Comments on the Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
- Public Comments on the Draft Policy
- New Federal Register Notice regarding the extension of the effective date for the Single IRB policy

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Questions?

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