



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



NIH sIRB Policy for Multi-site Research

Effective date: January 25, 2018

Applies to: U.S. sites for fully/partially NIH-funded multi-site studies as defined by policy (i.e. each site will conduct the same protocol involving non-exempt human subjects research)

Responsibilities: *"Applicants will be expected to include a plan for the use of an sIRB in their applications/proposals"*

- Multiple options for sIRB of record
- Institutions *not* required to serve as the sIRB of record

Exceptions:

- Career development (K), institutional training (T), and fellowship (F) awards; Where sIRB review would be prohibited by federal, tribal, or state law, regulation, or policy; If there is compelling justification

Funding: Certain costs for acting as a sIRB and for data coordination support for sIRB eligible for reimbursement as direct costs.



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."

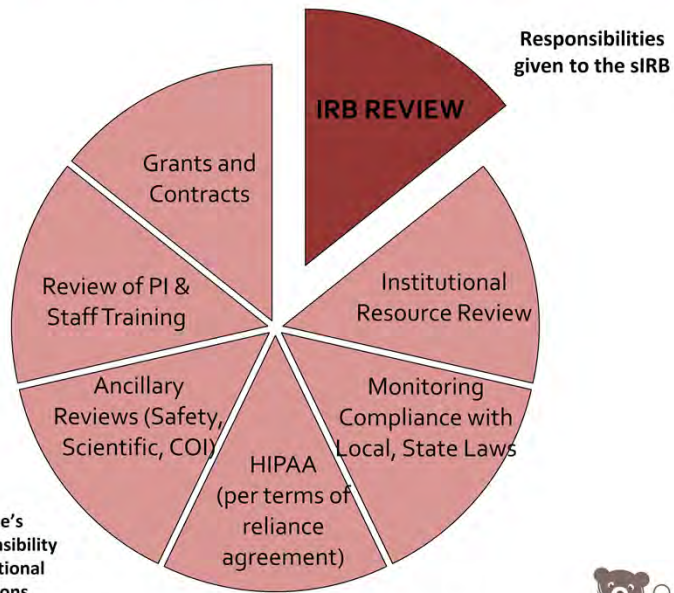
Multi-site study terms and definitions

- **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 reliance agreements, forms and processes



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



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

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

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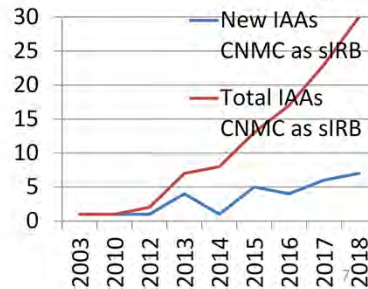


Current CNMC sIRB Activities

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



- 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**



Key responsibilities for lead PIs in multisite studies

- (1) managing communications across sites
- (2) collating participating sites' IRB submission materials
- (3) disseminating sIRB's determinations
- (4) facilitating submissions to the reviewing IRB
- (5) educating study teams on approved protocol amendments
- (6) reviewing institution's SOPs
- (7) disseminating sIRB determinations and other approved documents
- (8) identifying and reporting variability in study implementation across sites that must be communicated to the sIRB,
- (9) collection of information from sites to include in continuing review reports

This is not an exhaustive list!



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Responsibilities for lead PIs in multisite studies

- Significant start up costs & lead PI/research team level of effort
- Time and effort increase exponentially with addition of sites past a certain threshold, especially for non-minimal risk studies
- Access to DCC/data coordination resources & dedicated institutional infrastructure makes this role much more manageable
 - including: dedicated IRB resources, eIRB system enhancements

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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

Planning an NIH Funded Multisite Study? Now What?

Talk with OPHS during the *early planning stages* - we can help:

- Identify options for a sIRB - *IRB of record does not need to be at the lead PI's institution or even at a participating institution:*
 - Lead PI's institutional IRB
 - Performance site's IRB
 - Non-performance site's IRB
 - CTSA institutions funded to serve as Trial Innovation Centers (TICs): Duke /Vanderbilt; University of Utah, John Hopkins-Tufts
 - To request TIC sIRB services through the Trial Innovation Network use "submit the proposal" process at: <https://trialinnovationnetwork.org/>
 - Independent IRBs
- Developing a sIRB budget based on the NIH cost model
- Help with development of grant language
- Provide letters of support to accompany grant applications

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Planning an NIH Funded Multisite Study? Now What?

- **Discuss and understand the responsibilities of serving as:**
 - The lead PI (when CNMC is the sIRB)
 - The site PI (when CNMC is relying on another IRB)
- **Talk openly with collaborators *before* entering an agreement:**
 - Discuss sIRB options and costs
 - Discuss DCC support options and costs
 - Discuss and document the expectations
 - Develop communications plan

A clear and comprehensive communication plan is critical!

Template: https://smartirb.org/sites/default/files/Communications_Plan_Form.pdf



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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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