

Implementation of the NIH Single IRB Policy for Multi-Site Studies

Council on Governmental Relations Meeting
Washington Marriott Hotel
Washington, DC
February 23, 2017

Panelists

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Scope and Applicability

- Domestic sites of NIH-funded multisite studies using the same protocol for non-exempt research.
- Applicants to include a plan (i.e., selecting an IRB of record, confirming adherence, describing communications) in the application which will be incorporated as a term and condition of the award.
- Grant applications with receipt dates on or after September 25, 2017.
- NIH has not yet determined if administrative supplements will be made available to support the cost of the policy.
- IT infrastructure grants will not be provided at this time.

Resources

- Guidance on the use of direct and indirect costs for single IRB review – Costing guidance and developments will be addressed by NIH officials this afternoon.
 - Costing FAQs issued on February 17, 2017
- Frequently asked questions addressing applicability, proposal preparation, reliance agreements, site responsibilities, exceptions and other topics are available.
- National Center for Advancing Translational Sciences (NCATS) FAQs for selecting an IRB of record
- Reliance agreement templates (OHRP and NCATS SMART IRB)

NIH Single IRB Policy FAQs for Extramural Community

- Policy Background and General Requirements: FAQs 1 - 5
- Policy Terms and Definitions: FAQs 6 – 10
- Policy Applicability: FAQs 11 – 19
- NIH Grant Application/Contract Proposal Preparation: FAQs 20 – 28
- Reliance Agreements: FAQs 29 – 35
- Responsibilities of the Single IRB and Participating Sites: FAQs 36 – 46
- Award Considerations (Just-in-Time): FAQs 47 – 49
- After the Initial Award: FAQs 50 – 53
- Exceptions to the NIH Single IRB Policy: FAQs 54 – 58

Timing of plans and Reliance Agreements

A plan for sIRB is expected to be included in the application/proposal for funding.

- FAQ 20: In the NIH application/proposal for research funding, the applicant/offeror is expected to submit a plan describing the use of a single IRB. Where possible, the plan would identify the IRB that will serve as the single IRB.
- FAQ 47: If not provided in the application, the funding NIH IC may ask the awardee to identify the single IRB to be used and the plan to establish reliance agreements and communication between sites.
- NCATS (SMART) IRB Reliance Platform, has FAQs with tips for selecting a reviewing IRB.

Certification of IRB Approval

Typically occurs just in time. Per the FAQs, awards can be made without certification.

- FAQ 33: ...NIH recognizes that, for some studies, obtaining signed Reliance Agreements among sites may take longer to complete. In such cases, an acceptable time frame for establishing the single IRB and obtaining IRB approval will be agreed upon by the NIH funding Institute or Center and the awardee(s). Any award made without certification of IRB approval will include terms and conditions restricting all human subjects activities.

Reliance Agreements

Signed reliance agreements are not required prior to funding.

- FAQ 34: Signed agreements from participating sites will not be required to be in place prior to funding a multi-site study but must be in place prior to starting the proposed multi-site human subjects research.

Site Obligations

Local context issues and all current responsibilities except IRB review.

- FAQ 40: Participating sites need to inform the single IRB about relevant local context issues (e.g., state laws). A communication plan should be developed as part of the Reliance Agreement.
- FAQ 44: Except for the required regulatory IRB review, the HRPP at participating sites will be responsible for meeting all of its current related responsibilities described in the HHS regulations (45 CFR 46). These may include:
 - Reviewing conflicts of interest and radiation safety; ensuring that site investigators obtain informed consent; ensuring that site investigators meet local training requirements; overseeing the implementation of the approved protocol; and reporting local unanticipated problems, serious adverse events, and study progress to the single IRB.

Exceptions to the Policy

FAQ 54:

- When review by a single IRB would be prohibited by a federal, tribal, or state law, regulation, or policy.
- NIH will consider requests for other exceptions to the policy and will determine if there is adequate justification to grant an exception.
- Most exceptions are expected to be site-specific...all other sites conducting the same protocol will rely on the single IRB.
- NIH anticipates granting very few of these exception requests.
- Specific instructions on how to request an exception will be posted in the future.

COGR is developing a list of scenarios where use of sIRB would not be efficient or cost effective (e.g., community based research; SBIR/STTR).

Review of Grant Applications

FAQ 37 will presumably be changed to reflect recent changes to the Common Rule which eliminates the requirement for an IRB to review the grant application or contract. COGR will follow-up with NIH.

- FAQ37: As required by the HHS regulations at 45 CFR Part 46.103(f), the single IRB should also review the associated NIH grant applications or contract proposals.

Stanford University

Tentative plans for sIRB

- When serving as IRB of record, SU is considering using a commercial IRB
 - Protocols must be reviewed by active researchers
- Why commercial?
 - Avoid adding more staff
 - Complexity with various groups/entities
 - May avoid building new IRB system or module
- Will evaluate demand for being the sIRB of record
- Define the role of the IRB Office
 - Get others involved including hospitals, data security experts, privacy office, risk management

Stanford University

- Stanford can direct charge its IRB costs
 - IRB costs removed from the F&A pools in the late 1990s/early 2000s to facilitate direct charging IRB fees to clinical trials sponsored by pharmaceutical companies
 - NIH's Costing FAQs:
 - allow direct charging fees from commercial IRBs
 - allow direct charging fees from recipient institutions
- Will Stanford direct charge its IRB costs?

University of California Davis

SIRB PRACTICALITIES

- Have moved 1.5 FTEs to reliance registrations/agreements/setups (we will need more – other work may have to cease or turnaround times adjusted)
- Costing is easy and difficult at the same time
- We know what each action costs us – we don't know how many actions we will have to take per study
- TICs



KNOWN

- 1) Initial study set-up
- 2) Reliance Agreement negotiations (can estimate if # of sites is known)
- 3) Local context adaptation of ICFs/etc. and onboarding

UNKNOWN

- 1) How many modifications, reportable new events
- 2) How many changes to ICFs
- 3) Minimal vs At Risk

University of California Davis

sIRB PRACTICALITIES:

- 1) This is our indirect cost base year (taking IRB out of cost pools)
- 2) System already designed to accommodate – tested in multiple pilots
- 3) Communications with broader campus (BIG change in culture for IRB/SPO/researchers/staff)
- 4) Interactions with Sponsored Projects Office (TIMING and Workflow)
 - a) Checking with IRB re: budgets when sIRB is in proposal (FAQs say this can occur JIT – but does this mean sIRB fees will be in addition to budget ceilings?)
 - b) Subcontracting issues: If we are lead but another institution is the sIRB, are their fees included in the subaward budget? Can reliance agreements be embedded in the sub as a part of their SOW? Will these sIRB fees be charged at their research rates?
 - c) If sIRB is not a subawardee, will costs to another entity be budgeted as “service” or as a subcontract? (overhead at what rates on these charges?)

University of California Davis

sIRB PRACTICALITIES:

- 1) How to provide budgeting surety without running afoul of costing rules
 - 1) Scenario 1: Estimate based on past experience for at risk and minimal risk studies how many modifications/actions might be required. (eg. Assume 2 mods/year for minimal, 4 mods/year for at risk). At end of year, charge grant only for the number of actions taken. (if # is higher than guessed, IRB would not be made whole)
 - 2) Scenario 2: Estimate based on historical averages of actions and charge a flat annual rate which could be over or under actuals. Reconcile fee levels annually and adjust rates if costs come in over or under on an annualized basis. (Less \$ risk for researchers)
- 2) How/where to budget for sIRB in NIH protocols (FAQs give guidance but where does this go in the application forms?)
- 3) Reliance Agreement Templates – Everybody has one. UC system counsel suggesting an addendum to the SMARTIRB (current version deemed legally insufficient) so, national templates will still have to be negotiated for each site.

Washington University

Funding Source	WU Role	Consideration in choosing the sIRB	sIRB Options		
			WU IRB	IRB at Another Site	Independent IRB
Federally funded under NIH sIRB Policy (includes SBIR/STTR)	Prime Awardee	<p>The WU IRB will be considered first for the sIRB. However, a decision will be made on a case-by-case basis depending on the costs of sIRB review, number, type, and location of sites, complexity of the protocol, current capacity of the WU IRB, and ability to meet study review timelines.</p> <p>Only WU approved Independent IRBs may be used</p>	Yes	Yes	Yes
	Participating Site	<p>The Lead PI/Site will be responsible for identifying the entity to serve as the sIRB in the grant submission. This may involve consultation with other participating sites at the time of grant submission, or may be determined after award. If WU is considered as the sIRB, the same criteria under the Prime Awardee section would be assessed.</p>	Yes	Yes	Yes

Washington University

- Additional matrix for
 - Who is funding?
 - For profit, Not-for profit, No funding
 - Whose protocol is it?
 - Our Investigator, “Outside” investigator, sponsor initiated
- Researchers proposing to identify a primary independent when appropriate for federally-funded research
 - Identifying multiple independent IRBs to use for industry-sponsored research
- Will include direct costs when WU is sIRB

Washington University

- Considerations for local sIRB
 - May be able to provide lower cost option
 - Ability to provide IT infrastructure to support appropriate oversight
 - Transition staff to sIRB functions
- Hot topic at WU –defer other HRPP functions?
 - Review of serious/continuing noncompliance
 - Will outside sIRB agree to defer this back to local site?
 - Increased liability depending on willingness of sIRB to involve local institution

Emory University

- Use of Commercial IRB - Why?
 - Working with organization who is experienced in doing this
 - They have the systems, infrastructure, knowledge
 - Past/Current experience working with commercial IRB
 - They handle collaboration with other sites
 - Liability
 - Easy to identify costs of services

- Currently in Progress
 - Discussions regarding of workflow

WIRB's NIH Single Review Solution



A WIRB-Capgemini Group Company

WIRB's NIH Single Review Solution™

A comprehensive single IRB review solution that makes it easy for Academic Medical Centers and Investigators to comply with NIH's single IRB policy

- WIRB's Gold Standard Review Service
- WIRB's IRB Budgeting Tools & Smart Forms for NIH Grants
- Letter of support for grant submission
- WIRB writes customized ICFs for each participating institution with local requirements
- WIRB coordinates services for rapid submission & approval at each and every participating site
- PI visibility into the regulatory process and status at all participating sites

Why WIRB for NIH Grants?

The chosen IRB partner to 175 Academic Medical Centers

- WIRB's single IRB process is 100% compliant with NIH requirements
- Leverage WIRB's vast experience and customized approach the unique study startup requirements of each institution
- WIRB coordinates IRB submissions with participating investigators and local IRB offices
- WIRB's technology gives investigators real-time visibility and tracking of all NIH studies and approval documents
- WIRB ensures consistency and compliance with institution-specific policies and guidelines

How WIRB Serves as the Single IRB

Start up faster, enroll sooner, collect data more quickly

- WIRB's software rapidly assists in developing annual, ready-to-submit budgets for entirety of the grant
- WIRB rapidly negotiates customized ICF template for each site, if required (WIRB already knows the requirements of 175 Academic Medical Centers and nearly 2,200 hospitals)
- Rules-based IT systems to ensure tight coordination with each site's non-IRB processes for local approval
- WIRB teams are experienced in working with each site to coordinate submissions
- WIRB provides a single point of contact for accountability