Single IRBs for Multisite Studies: Costs to Consider
A forum for researchers, administrators and staff

Thursday, May 25, 2017  9-11 AM  2351 UC MSB

Topics include:
- the NIH mandate for single IRBs
- options in budget preparation
- allowable costs
- use of an independent, non-academic, single IRB

Panel Moderator: Mike Linke, PhD, Health Science Officer, Cincinnati VAMC and Chair, UC Institutional Review Board (IRB)

Panelists:
- Judith Spilker, RN, BSN
  Administrative Director, StrokeNet National Coordinating Center
- Patrick Clark
  Director, Government Cost Compliance, UC
- Eli Alford
  COO, Schulman and Associates IRB

Registration not required. Details: cctst.uc.edu

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health


June 21, 2016
Implementation September 25, 2017

Clinical and Translational Science

• “...for the majority of multi-site studies, the IRB at each participating site continues to conduct an independent review. This review adds time, but generally does not meaningfully enhance protections for the participants. This new NIH policy seeks to end duplicative reviews that slow down the start of the research.”

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
Purpose

• To enhance and streamline the process
• To reduce inefficiencies
• Ensure ethical principles and protections for human research participants are maintained
Scope and Applicability

- Domestic sites of NIH-funded multi-site studies whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program.
- Does not apply to career development, research training or fellowship awards.
- Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
- A plan for the use of an sIRB should be included in submissions.
- Acceptance of the submitted plan will be incorporated as a term and condition in the Notice of Award.
Definitions

• **Authorization Agreement** (Reliance Agreement)
  – documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating site relying on the sIRB.
• **A multi-site study** uses the same protocol to conduct non-exempt human subjects research at more than one site.
• **sIRB** is the single IRB of record that has been selected to carry out the IRB review requirements at 45 CFR Part 46 for participating sites of the multi-site study.
Roles and Responsibilities

• Applicant –
  – Expected to submit a plan describing the use of an sIRB that will be selected to serve as the IRB of record for all study sites.
  – The plan should include a statement confirming that participating sites will adhere to the sIRB Policy and describe how communications between sites and sIRB will be handled.
Roles and Responsibilities

- Applicant —
  - The applicant/offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB,
    - appropriate justification;
    - all such costs must be reasonable and consistent with cost principles, as described in the NIH Grants Policy Statement and the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs).
Roles and Responsibilities

• Awardees.
  – Responsible for ensuring that authorization agreements are in place
  – Copies of authorization agreements and other necessary documentation should be maintained in order to document compliance with this policy, as needed.
  – As appropriate, awardees are responsible for ensuring that a mechanism for communication between the sIRB and participating sites is established.
  – Awardees may delegate the tasks associated with these responsibilities.
Roles and Responsibilities

- **sIRB**
  - Responsible for conducting the ethical review of NIH-funded multi-site studies for participating sites
  - Expected to carry out the regulatory requirements as specified under the HHS regulations at 45 CFR Part 46
  - May serve as a Privacy Board
  - Will collaborate with the awardee to establish a mechanism for communication between the sIRB and the participating sites
Roles and Responsibilities

- Participating Sites
  - expected to rely on an sIRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46.
  - responsible for meeting other regulatory obligations, such as:
    - Obtaining informed consent
    - Overseeing the implementation of the approved protocol
    - Reporting unanticipated problems
    - Study progress to the sIRB
    - Ancillary reviews
Roles and Responsibilities

• Participating Sites
  – Must communicate relevant information necessary for the sIRB to consider local context issues
  – Policy does not prohibit any participating site from duplicating the sIRB. However, NIH funds may not be used to pay for the cost of the duplicate review.
Exceptions

- Exceptions to this policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.
- Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception.
- The NIH will determine whether to grant an exception following an assessment of the need.
Effective Date

- This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after September 25, 2017.
- Ongoing, non-competing awards will not be expected to comply with this policy until the grantee submits a competing renewal application.
# Single IRB of Record Models

<table>
<thead>
<tr>
<th>CIRB Model Type*</th>
<th>Examples</th>
<th>Model Coverage</th>
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<tbody>
<tr>
<td><strong>Central IRB</strong></td>
<td>National Cancer Institute (NCI) CIRBs - new model launched in 2013</td>
<td>Selected adult and pediatric cooperative group studies sponsored by the NCI</td>
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<td>Only one IRB of record designated to review research, often linked to a particular disease or research area.</td>
<td>VA Central IRB – launched in 2008</td>
<td>VA cooperative research</td>
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<td>University of Cincinnati – implemented in 2014</td>
<td>Research supported through the NINDS StrokeNet initiative</td>
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<td><strong>Independent (or Commercial) IRB</strong></td>
<td>Chesapeake Research Review, New England IRB, Quorum Review IRB, Schulman &amp; Associates, Western IRB</td>
<td>Not limited to any type or area of research; often used for multi-site studies that are fully industry-sponsored</td>
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<td>IRBs that are not part of organizations that conduct research and are generally part of for-profit entities.</td>
<td>IRB from a Greater Plains Collaborative (GPC) member institution</td>
<td>Patient-centered outcomes research conducted in common between at least 2 of the 12 GPC institutions</td>
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<td>IRB from Ohio IRB Consortium</td>
<td>Master agreement signed by key research institutions in Ohio</td>
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<td>IRB covered under Harvard Catalyst master agreement</td>
<td>Master agreement signed by many research institutions in New England and beyond</td>
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<tr>
<td><strong>Reciprocal Deferral IRB (Reliant IRB)</strong></td>
<td>IRBShare – launched in 2012 (now defunct)</td>
<td>Clinical research conducted by academic medical centers and/or CTSA sites</td>
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<td>Arrangements, frequently between regionally based institutions, in which a single IRB of record is designated from amongst the institutions for which a study is in common. Input from ceding institutions to the IRB of record is often a feature of this model.</td>
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<td><strong>Shared Review</strong></td>
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<td>Arrangements between institutions, wherein they share components of IRB review, such as reliance on a single IRB for initial review, but ongoing review (e.g. continuing review, changes of protocol, reportable events) reverts back to the institutional IRBs.</td>
<td>National Cancer Institute (NCI) CIRBs - original model launched in 2001</td>
<td>Selected adult and pediatric cooperative group studies sponsored by the NCI</td>
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Examples of UC Serving as a Reviewing IRB

- UC/CCHMC MOU
- Consortium of Greater Cincinnati IRBs
- Ohio Collaborative
- Private Practice Group Protocol
- StrokeNet CIRB
Study Characteristics

- Number of sites
- Location of sites
- Type of study
- Sponsor
- Length of study
- Type of sites
- Coordinating support
- IND/IDE
The Reliance Agreement: Is life getting easier?

- Master reliance agreements
  - SMART IRB
  - IRBchoice
- One-off reliance agreements
- Network reliance agreements (StrokeNet, NeuroNext, PETAL, NCI, TrialNet)
- Regional reliance agreements