Single IRBs for Multisite Studies: Costs to Consider

A Central IRB Perspective

Eli Alford, COO, Schulman IRB
About Schulman IRB

- Established in 1983
- Superior audit history with FDA—six consecutive audits with no findings
- 21 CFR Part 11 compliant electronic systems
- Compliant with FDA, OHRP and Health Canada requirements
- Full Board meetings five days a week
- Dedicated daily expedited review of qualifying minimal risk protocols and changes to research
Eli Alford
Chief Operating Officer, Schulman IRB

- With Schulman since 2011
- Provides strategic leadership for Schulman by establishing plans, policies and performance goals that support client needs and ensure protection of human research subjects
- Retired Army colonel with over 25 years of service in combat arms leadership and research/analysis roles
- Experience as a Contracting Officer’s Representative under federal acquisition regulations and program manager for federal contracts on the vendor side.
- Experience at a global CRO in clinical operations management, business improvement, proposals, and corporate development
- Lean Six Sigma Black Belt
- Certified IRB Professional
- BA, MS, former Harvard Kennedy School Fellow
### NIH Policy—Independent IRB Scenarios

<table>
<thead>
<tr>
<th>#</th>
<th>Awardee</th>
<th>sIRB</th>
<th>Participating Sites</th>
<th>How sIRB Costs Should Be Able to Be Charged</th>
</tr>
</thead>
</table>
| 3 | Institution A  
• prime awardee  
• conducting the study | Independent IRB | Institution A + 14 subawardees | • Primary activities are charged as direct costs. Institution A will commission an Independent IRB to serve as the sIRB and reviews by the Independent IRB are charged as Institution A’s direct costs.  
• Secondary activities for Institution A and the 14 participating sites may be charged as Institution A’s direct costs. |
| 7 | Entity B  
• prime awardee  
• not conducting the study but engaged | Independent IRB | 14 subawardees | • Entity B will commission an Independent IRB to serve as the sIRB.  
• Primary and secondary activities may be charged as Entity B’s direct costs. The sIRB will also perform IRB review for Entity B, which is considered engaged as the prime awardee |
| 9 | 15 individual awardees | Independent IRB | 15 awardees | • Primary and secondary activities may be charged as each of the 15 sites’ direct costs.  
• The lead PI’s institution will commission an Independent IRB to serve as the sIRB. The 15 sites may include the cost of IRB review in their individual budgets and each will pay the Independent IRB for services rendered. |

What Kind of Contract?

- Overview of contract types
  - **Firm-fixed-price**: contractor owns the risk
  - **Time and materials (hourly)**: customer owns the risk
  - **Cost-plus (award fee or fixed fee)**: balance between the two above
  - **Fee-for-service**: à la carte

- Schulman operates under fee for service model

- Why? Industry standard (independent IRBs and CROs)

- Use of the other models may evolve

*How Do You Plan Fee-for-Service?*
Drivers for IRB Budget Estimation

<table>
<thead>
<tr>
<th>Study duration</th>
<th># protocol-level recruitment materials</th>
</tr>
</thead>
<tbody>
<tr>
<td># sites</td>
<td># site-developed recruitment materials</td>
</tr>
<tr>
<td># protocol amendments (based on similar studies)</td>
<td># study-related materials (e.g. diaries)</td>
</tr>
<tr>
<td># site-level amendments</td>
<td># translations (what language/how many)</td>
</tr>
<tr>
<td># sub-studies</td>
<td>Who will be responsible for translations</td>
</tr>
<tr>
<td># informed consent/assent documents</td>
<td>Other services (e.g. privacy board)</td>
</tr>
</tbody>
</table>

- A single study is a fairly straightforward math problem
- The risk is under-estimation
- And then there are the applicable non-IRB services internally or externally provided (Biosafety, COI, Radiation Safety, etc.)
Network Case Study

Situation: $25M/5-year NIH RFA for a therapeutically focused research network

- How many studies and what kind? Unknown
- Single IRB required as part of network infrastructure

How much should applicants budget for IRB services?
Network Case Study

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- Budget worst case and potentially under-fund other areas?
- Budget best case and hope it’s enough?
- How about: Talk to NIH and ask what they expect?
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Result: *In this case*, NIH recommended budgeting a percentage of the cost in the network grant, and each study grant budgets the remainder as details become known.
A Brave New World

- Budgeting independent IRB services for multi-site research is not new
- What’s new is independent IRB services as an allowable direct cost
- If using an independent IRB, use one that will help with budget estimation and execution
- Multi-site research: what independent IRBs do best