POINTS TO CONSIDER:

Fees and Costing Models under the NIH sIRB Policy

A guide for Reviewing IRBs

Fees and Charging Models Working Group
of the SMART IRB Harmonization Steering Committee

April 2018

Harmonized: This document underwent a review and input process from February 2017 to April 2018 and has now been finalized.

Contents

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INTRODUCTION

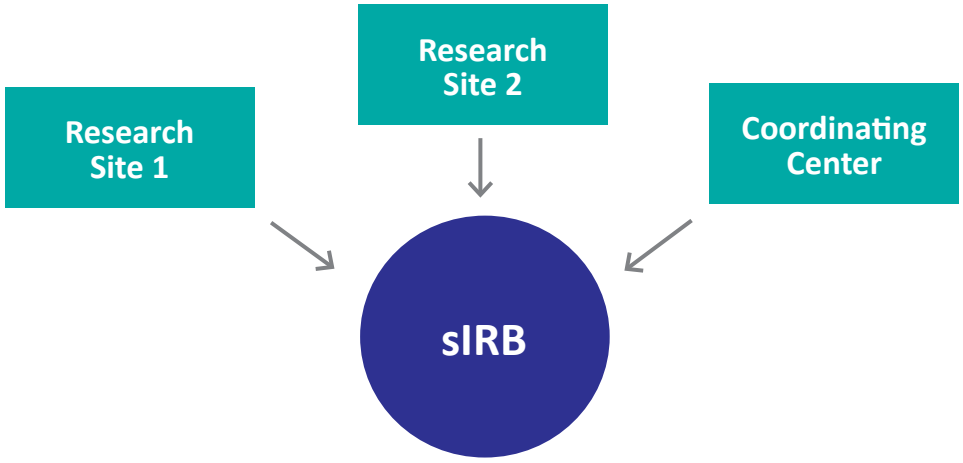
Both the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) allow a site to use an external IRB to review and provide oversight for human subjects research that is conducted by local investigators. Particularly, in the context of multisite research, both NIH policy and the 2018 HHS Common Rule require use of a single IRB (sIRB) to provide oversight for all participating research sites. A typical model is reflected in Figure 1.

Driven by the change in NIH policy requiring sIRB review of multisite research, those IRBs that choose to provide sIRB services to other sites have the opportunity to charge fees to federal grants for such services.

This document provides Points to Consider (PTC) for Reviewing IRBs such as:

1. **Factors in deciding whether to charge fees**
2. **Methodologies to determine actual IRB costs**
3. **Case scenarios on structuring and justifying fees**
4. **Information on federal regulations that impact both direct and indirect IRB costs**

FIGURE 1: EXAMPLE sIRB MODEL



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DEFINITIONS

DIRECT COSTS: Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7_cost_consideration.htm)

INDIRECT COSTS: Also referred to as Facilities and Administration (F&A) or overhead costs, these are necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7_cost_consideration.htm)

PRIMARY ACTIVITIES: Activities associated with conducting the ethical review of the proposed research protocol that will be carried out at all of the participating sites and the review of the template informed consent document describing the study. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html)

RELYING INSTITUTION: An institution that cedes IRB review to a Reviewing IRB for the purpose of obtaining IRB oversight of human subjects research conducted at its site.

REVIEWING IRB (also called an sIRB or Reviewing sIRB): An IRB that has taken on the role of the "IRB of record" for another research site conducting human subjects research.

SECONDARY ACTIVITIES: Activities associated with review of site-specific information, such as investigator qualifications, institutional capabilities, state/local regulatory requirements, and community ethos. Following initial approval, there are additional activities to fulfill IRB oversight responsibilities, including reviewing reportable events (e.g., unanticipated problems, protocol deviations), and, as necessary, reporting them to the Office for Human Research Protections (OHRP) and the funding Institute or Center; receiving and reviewing any complaints that arise regarding conduct of the study; notifying all sites of serious or continuing non-compliance and all other determinations; and communicating with participating sites on matters related to sIRB determinations.
(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html)

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POINTS TO CONSIDER (PTCs) for the REVIEWING sIRB

KEY CONCEPTS

- Whether a cost is allowable depends upon what is included in the organization's F&A rate (if any), the organization's federal award for the study, and the type of activity generating the cost.
- Allowable costs must be appropriately justified in compliance with federal regulations at 45 CFR 75 Subpart E.
- Allowable costs may differ from organization to organization or even study to study.
- In general, primary activities should be charged as indirect costs if those activities are included in an organization's Federally-approved indirect cost rate agreement. Secondary activities may be charged as direct costs, with appropriate budget justification.
- Reviewing sIRBs that plan on direct charging any costs should work closely with their organizational financial administrators and sponsored programs offices to ensure fees are appropriate and meet federal grant regulatory requirements.

Whether a direct cost for sIRB review is allowable on a federal grant depends upon several factors. If the sIRB institution is an entity that negotiates a federal Facilities and Administration (F&A) rate and the entity includes IRB review costs as part of their F&A rate, then fees that meet the definition of "Primary Activities" cannot be charged as a direct cost. However, if an entity has removed or has never included IRB costs in their F&A rates, then both primary and secondary charges may be eligible, with appropriate justification, as a direct fee on a federal grant (see Figure 2).

FIGURE 2: ALLOWABLE DIRECT AND INDIRECT COSTS

Allowable Costs?	**IRB in F&A**	**IRB *not* in F&A**
Direct Cost	Secondary Activities	Primary & Secondary Activities
Indirect Cost	Primary Activities	None

PTC #1: Does your organization include IRB costs in the F&A rate?

Costs for conducting research under a federal award may be covered as direct costs or recovered via indirect costs. Costs must be allocated as either direct or indirect; they cannot be both. If the organization is assuming the role of a Reviewing sIRB, the determining factor in deciding if any sIRB costs may be charged as direct costs on a federal funding mechanism depends on whether or not the organization includes the IRB review in its F&A cost rate.

Suggested steps to determine the correct allocation of sIRB services at your organization:

1. Contact the appropriate office or administrative official in your organization who is engaged in the F&A rate negotiation process and/or provides consultation on allocable costs for federal grants.
2. Determine if the federal F&A rate for your organization includes any costs of IRB services; and, if yes, what IRB costs are included.

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✔ *YES – your organization's F&A rate includes IRB services:*

If the costs of IRB services are already included in your F&A rate, you will need to determine, in collaboration with appropriate organizational officials, whether this is still the appropriate choice for your role as a Reviewing sIRB.

PROs: The Primary Activities for sIRB review are considered covered under F&A and only Secondary Activities will be charged as direct costs on the research budget. This could translate into a benefit for the researcher as more allowable direct costs would be available for their use in conducting the study, as opposed to having to support all sIRB costs through direct funds.

CONs: Depending on the cost reimbursement structure at your organization, this approach may result in a lower reimbursement rate for sIRB Primary Activity costs.

sIRB review services will need to be identified and justified in a detailed manner as either Primary or Secondary. The NIH has provided definitions of these terms, however each organization needs to conduct a detailed analysis based on how the sIRB operates and conducts reviews for other sites. (See PTC #2)

✖ *NO – your organization's F&A rate does not include IRB services:*

If your organization has never included IRB services or has removed all costs of IRB services from your F&A rate, your organization will need to determine whether this is still the appropriate choice for reimbursing your role as a Reviewing sIRB.

PROs: A potential benefit of this approach is that both the Primary and Secondary Activities for sIRB review are allowed as direct costs on the research budget. Depending on your organization's cost reimbursement structure, this may result in more appropriate reimbursement to the sIRB for all review activities.

Primary and Secondary Activities do not need to be differentiated to determine which are allowed as direct costs. However, sIRBs may still need to carefully track all services for the purposes of justifying cost rates and to comply with federal costing principles. (See Examples #1-4)

This approach assigns all secondary costs to the correct study.

The organization has the ability to establish an appropriate costing model.

CONs: The researcher may need to commit more of the direct costs in their grant budget to paying for sIRB review and thus potentially reduce the amount available for conducting the study.

This approach can be time-consuming as it requires extensive documentation and staffing resources, including a process to trace each review action.

Budget justification may be more complex.

Once you have established whether your F&A rate includes IRB services, see Figures 3 and 4 below to determine allowable costs. Additional guidance and information is available in Resources at the end of this document.

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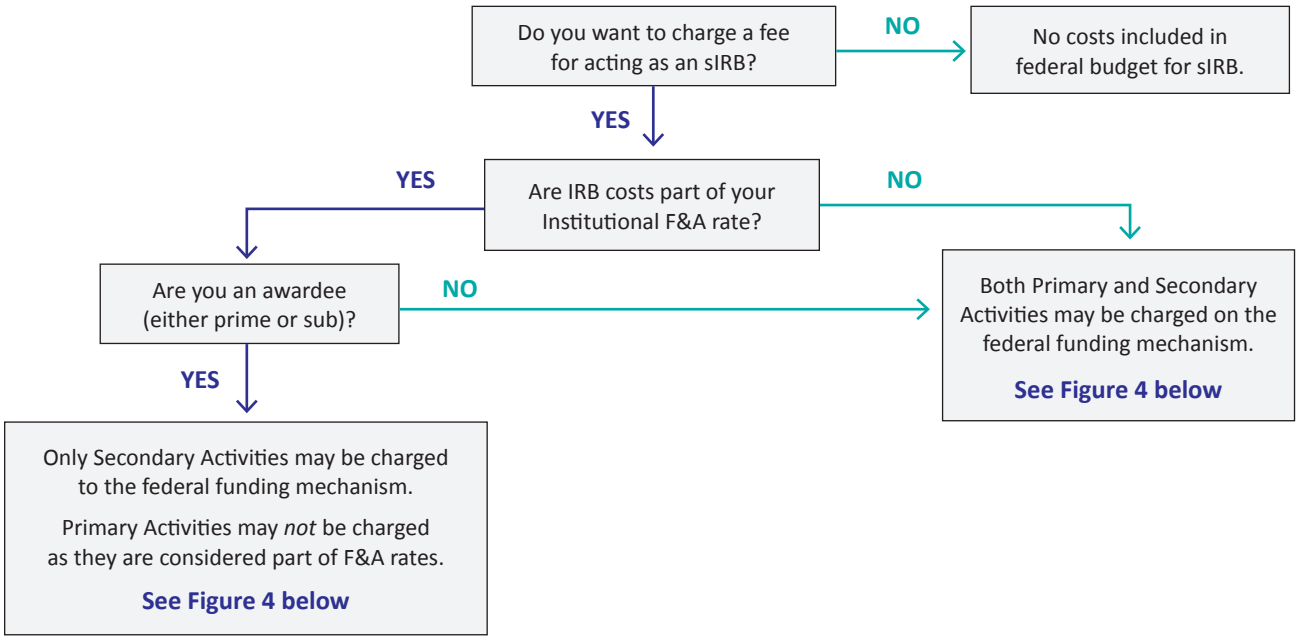
FIGURE 3: FLOWCHART TO DETERMINE ALLOWABLE COSTS UNDER FEDERAL REQUIREMENTS



Allowable Costs At-a-Glance

Figure 4 outlines sample activities for which you may charge, based on your organization's indirect- or direct-cost model. Your organization may decide to charge for some or all of these activities, or bundle activities together for ease of accounting. These activities are not exhaustive.

FIGURE 4: SAMPLE OF ALLOWABLE COSTS UNDER INDIRECT AND DIRECT COST MODELS

Primary Activities

	Is this an allowable cost?	
SERVICE OR TRANSACTION	INDIRECT COST MODEL	DIRECT COST MODEL
Initial Review of Protocol	✖	✔
Review of Local Investigator	✖	✔
Overall Protocol Modifications	✖	✔
Annual/Continuing Review	✖	✔
Approval of Study-wide Translated ICFs	✖	✔
Reportable events* (at Reviewing IRB's local site)	✖	✔
Overall Study Closeout	✖	✔

Secondary Activities

	Is this an allowable cost?	
SERVICE OR TRANSACTION	INDIRECT COST MODEL	DIRECT COST MODEL
Addition of sites 2-xx *Excludes local site*	✔	✔
Annual/Continuing Review of sites 2-xx *Excludes local site*	✔	✔
Reportable events* at sites 2-xx	✔	✔
Site-specific Modifications	✔	✔
Change of Relying Principal Investigator	✔	✔
Approval of Site-specific Recruitment Documents	✔	✔
Audit *As requested*	✔	✔
Site Closeout	✔	✔
New IRB Reliance Agreement	✔	✔

**Consider removing any disincentive to report by not charging.*

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PTC #2: Identifying Activities to Include in a Fee/Costing Model

Once your organization has determined whether Primary and/or Secondary Activity costs will be allowable as direct costs for your grants, you should determine which activities to include in your fee/costing model. The list below identifies examples of activities that you may consider including in a fee/costing model. Whether or not each cost can be charged as primary or secondary depends on the definitions provided in the NIH notice. Whether each cost is allowable as a direct or indirect cost depends on F&A status, funding mechanism, and organization type (e.g., academic vs. independent). Given the many considerations in the development of an organization's F&A rate, NIH recommends consulting with your appropriate federal agency on indirect costs prior to proposing any changes.

Please note: This list of activities is not exhaustive

1. **Negotiating a reliance agreement to serve as the sIRB for the multisite study:**

   If the SMART IRB Agreement or another agreement is already in place among the sites, these costs may not be allowable.

2. **Negotiating an addendum or additional agreement (e.g., a protocol-specific addendum to document additional terms of the agreement) to an established master agreement.**

3. **Initial Review of Primary Activities:**

   Approval of the study-wide protocol, a template consent document, or recruitment materials for use by all participating sites.

4. **Initial Review of Secondary Activities:**

   Any or all of the following reviews may be considered in assessing fees for each participating site:

   a. Investigator qualifications.
   b. Study site qualifications and capabilities.
   c. "Local context" information such as state and local laws, or regulatory requirements and culture of the community pertinent to the conduct of human subjects research.
   d. Site-specific research activities such as unique recruitment or enrollment approaches (e.g., social media, eConsent), site-specific consent documents or recruitment materials, or review of translated consents and provision of short-form consents.
   e. Individual conflict of interest (COI) determinations and/or review of management plans from sites.
   f. Institutional COI determinations and/or review of management plans from sites.
   g. Reviews required as a HIPAA privacy board for waiver or alteration of authorization for research purposes, if the sIRB has agreed to fill this role. (The review of authorization language included as part of the consent may be considered for inclusion; however, if the authorization is a separate document, the IRB is not required to review it.)

5. **Continuing Review as a Primary Activity:**

   Approval of the study-wide progress report, renewal of the template consent document, or recruitment materials used by all participating sites.

6. **Continuing Review as a Secondary Activity:**

   Review of site-specific progress reports, renewal of site-specific consents or recruitment materials, communication of IRB determinations to each site.

7. **Modifications as a Primary Activity:**

   The cost of review and approval of a study-wide protocol amendment, revised consent template, or recruitment materials, study-wide notifications to subjects, etc.

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8. **Modifications as a Secondary Activity:**

   Costs associated with providing IRB determinations, including the approval and distribution of materials related to the amendment, to each research site. In addition, site-specific amendments such as changes in the study protocol to accommodate a situation at one site (e.g., changes to staff, local recruitment materials, or local consent language).

9. **Reportable Events at sites as Secondary Activities:**

   The sIRB may consider including the following events that occur at sites in a fee/costing model. Reportable events that occur at the reviewing IRB's local site may or may not be allowable. Each of these items could be further divided into activities such as investigation, IRB determination review, reporting to federal regulatory authorities and funding entities, and providing determinations and documentation to participating sites.

   a. Unanticipated problems involving risks to subjects or others
   b. Noncompliance (or allegations of noncompliance), protocol deviations or violations
   c. Serious and/or continuing noncompliance
   d. Subject complaints
   e. Emergency use reports

10. **Study Closure as a Primary Activity:**

    The costs of approving study-wide communication and closing the protocol.

11. **Study Closure as a Secondary Activity:**

    If individual sites close, requiring site-specific review, determination, and/or communication.

PTC #3: Example Methods to Determine Actual sIRB Costs

While financial and accounting literature describe several methods used to calculate fee schedules, this document offers three example methods that have been successfully used at organizations providing sIRB services. **Your organization may choose to use or adapt one or more of these approaches based on organizational characteristics, or develop your own model.** Regardless of the approach you use, the methodology must be identifiable, reasonable, auditable, and transparent.

Method #1: Conduct a Time Study

Conduct a time study for each activity for which you have decided to charge a fee. Have the staff member(s) who are involved track the time they spend conducting that particular activity. You may average the time spent over a series of such activities to obtain a cost per activity (based on salary/pay rate for the individual). This is a simple (though time-intensive) method. A more complex and comprehensive approach would be to also factor in the proportional costs that support that staff member conducting the activity, such as cost of space, utilities, training, office supplies, systems, etc.

See Example #1

Method #2: Divide Total IRB Costs by Activities

Starting with total IRB costs, count the total number of activities supported by those costs and divide total costs by the number of activities to get a per-activity cost. This has the benefit of including all costs associated with an IRB and supporting administrative activities. This per-activity cost may then be used, along with an estimate of how many of each type of activity would occur over the life of a study, to estimate costs that you might include in a grant budget.

See Example #2 and Example #3

Method #3: Use Weighting and Variance Factors in Current- and Future-State Costing Models

Create a weighting factor for each type of form for which you choose to charge a fee, based on the average amount of time

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required to process that form. Use the weighting to distribute the total costs of operating the IRB and its administrative support unit across different form types (or fee units). This per-form cost can then be further adjusted based on key variance factors that may impact average processing times for sIRB activities, such as more effort for reviewing sites with different state laws or additional staff time to educate community sites participating in a multisite study. The model feeds directly into a grant or project budgeting tool that identifies costs per site over varied grant or project periods.

See Example #4

PTC #4: Other Factors to Consider in a Fee/Costing Model

Identifying the types of IRB services or activities that may be included is an important first step in developing a fee/costing model for charging sIRB fees. However, additional key factors will need to be considered in determining the overall model and ultimately, the rates your organization will charge for these services.

1. Some of the activities identified in PTC #2 consist of multiple components that could be divided and charged individually versus charging a flat rate for the overall activity. For example, item #3 discusses approval of a study-wide consent template as an activity that would be considered a primary activity for initial review. For a study that requires approval of multiple consent mechanisms, (e.g., separate adult, parental permission and child assents) an organization could choose to either charge a separate fee for each or a single fee, regardless of the number of consents/assents required.

   Conversely, you may consider bundling certain activities/fees for ease of collection. For example, bundling an average of three study-wide modifications each year in your initial and continuing reviews may make fee collection less onerous.

   Organizations will need to weigh the cost/benefit of charging for each activity versus bundling or charging flat rates. The greater the number of types or volume of activities, the more complex the accounting and administrative support needed to implement and document the fee/costing model. And presumably, there will be a higher cost to implement and maintain the system.

2. Some of the activities in PTC #2 may also be considered either Primary or Secondary, depending on how your sIRB conducts their reviews. For example, if it is the lead PI's responsibility to gather all continuing review information for each site and submit a single, comprehensive report to the sIRB, then this may qualify as a Primary Activity. However, if each site individually submits its continuing review for sIRB review, it may be more appropriately justified as a Secondary Activity for each site review. A subject matter expert with expertise in the operational details of the sIRB review process should be involved in determining how to delineate each activity for costing purposes.

3. A portion of your F&A costs may be attributable to Secondary Activities. If those costs are not part of your F&A rate, you may consider including them in fees for Secondary Activities. Be sure to work with the appropriate office or administrative official in your organization who is involved with the F&A rate negotiation.

PTC #5: Independent/Commercial IRBs and their Fees

If none of the participating institutions in a multisite study has the capacity or willingness to serve as the Reviewing IRB, an independent IRB may be used to satisfy the single IRB requirement. Independent IRBs typically have robust infrastructure and efficient processes to oversee multisite studies, but those capabilities come at a cost. Fortunately, those fees may be passed through to the grant, including an administrative fee from your institution.

Most independent IRBs charge for each transaction, so it is important to include a sufficient number of such transactions in the study budget to cover fees over the life of the study. This includes activities such as:

- Initial review of study
- Review of each PI
- Review of multiple consent documents for a study or additional fees for assents or other types of consent materials

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- Translation fees
- Review of recruitment materials
- Modifications/amendments (e.g., updated protocol or investigator's brochure, new consents, recruitment materials)
- Continuing reviews
- Site addition
- Reportable events
- Site/study closure

PTC #6: Developing a Grant Budget

Once a fee model is developed, there should be sufficient information to efficiently and consistently create a budget proposal for a grant. *(See Figure 8)*

Depending on how the model was developed, the following additional items may be used as variance factors to increase or decrease the proposed budget:

1. Number of sites.
2. Proposed length of the study (used to determine number of continuing reviews or estimate the number of other IRB review activities).
3. Number of modifications. These may vary greatly from study to study. Other considerations include the study risk level, type of study (clinical versus observational), population, and other factors when projecting the number of modifications to account for in a budget estimate for a grant submission. An organization could also use historical data to estimate the number of modifications that typically occur over the course of similar types of studies.
4. Number of reportable events. These may vary greatly from study to study. You may consider the study risk level, type of study (clinical versus observational), population, and other factors when projecting the number of reportable events to account for in a budget estimate for a grant submission. An organization could also use historical data to estimate the number of reportable events that typically occur over the course of similar types of studies.

   Note: Many organizations do not charge for reportable events to encourage reporting of important risk-related information as soon as possible.
5. The location of sites (i.e. workload related to review of local context).
6. Number of reliance agreements and/or addenda requiring negotiation.

PTC #7: Implementing Fee Charging for Funded Awards

Once a fee/costing model is developed and used in proposed grant budgets, your organization will have some key decisions to consider should the grant be funded. Developing a fee implementation plan will be helpful in preparing investigators at your site and any participating sites as to when and how charges will occur.

1. A grant may be funded at a level below the requested budget amount; when this occurs, the organization should have a plan for whether sIRB fees will be reduced or whether they will be maintained at the budgeted level. If the number of sites is reduced, proposed fees for review of those sites would be expected to be eliminated.
2. The organization will need to determine how often cost rates will be adjusted. In the case where rates adjust after a grant is submitted but prior to award, the organization will need a plan for whether the rates in effect at submission or at award will be charged. Similarly, if rates adjust at least annually, the organization will need to plan whether fees will change over the life of a budget award. Amounts above the budget would need to be rebudgeted from other parts of the grant or funded from other resources.

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3. The estimated number of modifications or reportable events, or other estimates used to construct the proposed grant budget will likely not match the actual number of activities during the conduct of the study. Approaches to handling these situations may include:

    a. Charging only for the number of activities proposed in the budget, regardless of actual number of activities.

    b. Charging for actual number of activities, regardless of what was proposed in the budget. Amounts above the budget would need to be rebudgeted from other parts of the grant or funded from other resources.

    c. Providing for some flexibility with regard to proposed number of activities and only charging for those outside of a pre-determined variance factor (e.g., no additional charges as long as number of activities stay within a 10% variance).

PTC #8: Recharge Centers and Specialized Service Centers

After your organization has developed a fee/costing model, one method of handling the sIRB fees is through the use of a Service/Recharge Center (SRC). SRCs are operating centers within institutions established for the primary purpose of providing specialized fee-based services to researchers and the institution (although services may be provided on an incidental basis to external users). sIRB operations that are set up as an SRC are designed to recover the costs of their operations primarily through charges to internal users.

Because of the risk of incurring large penalties for improper use of an institution's not-for-profit status, some institutions are cautious about allowing external use of service center facilities. Inappropriate outside use of service center facilities could jeopardize an institution's tax-exempt status for various purposes, give rise to claims of warranty and other liabilities, or appear to involve unfair pricing in relation to service providers in the local business community.

Situations may arise, however, where the unique nature of a service center's products or services — in this case, specialized sIRB services — justify allowing external users limited access to those services. Expanding a service center's volume of business may enable the service center to lower its rates, benefiting internal users.

The following procedures should be addressed before setting up an SRC to recover sIRB fees. As Benjamin Franklin cautioned, "an ounce of prevention is worth a pound of cure."

- Become familiar with the standard business procedures and recordkeeping practices at your institution, including handling of invoices, billing, and accounts receivable.
- Determine whether your institution has a formal process for establishing internal and external recharge rates. Most organizations will have policies for allowable direct costs and taxable income.
- Become familiar with the basic principles of the relevant federal rules and regulations governed by the Office of Management and Budget (OMB). The OMB recognizes two types of non-profit organizations: educational institutions (universities and colleges) and nonprofits (foundations, corporations, associations, cooperatives), as opposed to commercial organizations (COMs).

Institutions using SRCs to provide financial oversight over their sIRB operations are responsible for establishing written operating procedures to ensure billings to institutional accounts and federal programs are reasonable and allowable.

Service/Recharge Center Criteria

- Provide specialized sIRB services to institution
- Request to establish a recharge center is submitted to appropriate institutional office for financial and business services
- Costs used to determine billing rates must be identifiable and auditable
- Billing rates apply uniformly to all institutional users

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- Billed rates must not exceed actual costs
- Managed according to governmental accounting standards
- Subject to federal and state audits as well as institution's internal audit
- Should operate on a break-even basis

The NIH will:

- Determine whether specialized service facilities (called recharge centers) at colleges and universities have rate schedules that ensure that amounts charged are reasonable and consistent and comply with the standards for such facilities.
- Determine the necessity for and reasonableness of the recharge centers' expenses. Recently, the Office of Inspector General identified problems in this area. Recharge centers at universities operate as in-house enterprises and are used to finance, account for, and report on the provision of goods and services to other operating units. Standards for specialized service facilities are found in OMB Uniform Guidance §200.468.

PTC #9: Engaging Other Organizational Offices and Administrators

The development and implementation of fee and costing models for sIRB review will likely require the collaborative efforts of several administrative offices and organizational officials. It will be important for organizations planning to develop and implement an sIRB service to ensure all key stakeholders are included in the development and implementation process. Examples of these key stakeholders may include:

1. Sponsored programs/projects offices
2. Finance offices and administrators
3. Contracting offices and personnel
4. Departmental administrators
5. IRB and human research protection offices and administrators
6. Organizational/institutional officials
7. Research administrators

Although the development and implementation of new or revised services within an organization will differ across organizations, there are several common tasks that should be considered in working with different parts of your organization:

1. Identify IRB costs included in F&A rates.
2. Differentiate indirect vs. direct costs.
3. Ensure correct terms related to sIRB fees are included in subawards and contracts.
4. Define allowable direct costs for a specific project to be included in the project budget.
5. Ensure costs incurred for the same purpose in like circumstances are treated consistently as either direct or indirect costs.
6. Consult when budget adjustments are needed at the time of award or during the conduct of the study.
7. Negotiate revised F&A rates.

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Example #1: Time Analysis
StrokeNet

The StrokeNet Central IRB (SN CIRB) chair, vice chair, and staff estimated the amount of time they spent on the various review tasks during the first few studies that were reviewed by the SN CIRB. These results were then used to estimate the hours and percent efforts that the members of the SN CIRB team spend on each task. The results were used to determine the percent of effort per site. These data are presented in Figure 5, below.

The time study included the amount of time spent on pre-submission, submission, review, and approval of the protocols, continuing reviews, amendments, and reportable events at the lead site and each participating site. The lead site is the location of the lead investigator on the study. The participating sites are the additional research locations.

Many of the SN CIRB tasks are similar to those performed during processing our local protocols; however, due to the remoteness of the research sites and their lack of familiarity with the SN CIRB process, most require more time. There are also tasks specific to the SN CIRB, such as processing of initiation amendments for participating site approvals. A primary source of the additional work on the SN CIRB is related to the CIRB staff who enter the study information into the electronic protocol administration system (ePAS) for the StrokeNet investigators. To develop accurate CIRB budgets, consider both the additional tasks and time related to processing protocols for CIRB review and approval, and the individuals at your site who will perform the various tasks.

The budget calculators presented here are based on the individuals that perform the tasks for the SN CIRB review, as detailed below.

The SN CIRB Chair performs:

- Initial pre-board review of new protocols to identify any significant concerns prior to full board review.
- Expedited review and approval of initiation amendments for addition of participating sites.
- Initial review of protocol amendments prior to full board review and approval.
- Continuing review of lead site protocol prior to full board review.
- Expedited review and approval of participating site continuing reviews.
- Miscellaneous ongoing communication with participating sites.

The SN CIRB Human Protection Administrator:

- Performs administrative review of submissions and processes them for review by the CIRB.
- Facilitates any clarifications needed during the review process.
- Prepares the approval documents.
- Prepares CIRB meeting minutes.

The SN CIRB Liaison:

- Coordinates submission of the studies to the CIRB.
- Ensures study documents are appropriately submitted in ePAS.
- Ensures required documents are available for CIRB review.
- Facilitates communications between the research sites and the CIRB.
- Conducts training for all submissions from preforming sites at investigator meetings.
- Participates in coordinator webinars and StrokeNet operations meetings as requested.
- Assists in writing and reviewing SN SOPs.
- Assists in and fields conference calls and questions from performance sites' IRBs.

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SN CIRB Coordinator:

- Assists CIRB liaison.
- Ensures submissions are complete.
- Enters study information into ePAS.
- Facilitates communications between the CIRB and research sites.

SN CIRB Vice Chair:

- Reviews all potential unanticipated problems involving increased risk to subjects or others reportable events.

FIGURE 5: STROKENET - CALCULATING PERCENT EFFORT

Hours per Action

	IRB Chair		Human Protection Administrator		CIRB Liaison		CIRB Coordinator		IRB Vice Chair	
	year 1	year 2-? per Site	year 1	year 2-? per Site	year 1	year 2-? per Site	year 1	year 2-? per Site	year 1	year 2-? per Site
Lead Site Protocol Approval	4		10		10		5			
Initiation Amendments for Participating Site Approvals	1		5		4		4			
Continuing Review Approval - Lead Site		2		2		3		3		
Protocol Amendments -1 amendment per Site per year		1	2	2	2	2	2	2		
Administrative Amendments 5 per Site per year			5	5	5	5	5			
Continuing Review Approval - Participating Site		1		1		1		1		
Reportable Events - 1 events per Site per year			1.5	1.5	2.5	2.5	2	2	1	1
Ongoing Communications with Sites		1			10	10				
sum participating site hours	1	3	13.5	9.5	23.5	20.5	13	5	1	1

Percent Effort per Site based on 2080 Hours

lead site	0.19%	0.10%	0.48%	0.10%	0.48%	0.14%	0.24%	0.14%		
per participating site	0.05%	0.14%	0.65%	0.46%	1.13%	0.99%	0.63%	0.24%	0.05%	0.05%

Examples of Percent Effort based on Number of Study Sites

# of Sites	IRB Chair		Human Protection Administrator		CIRB Liaison		CIRB Coordinator		IRB Vice Chair	
	year 1	year 2-? per Site	year 1	year 2-? per Site	year 1	year 2-? per Site	year 1	year 2-? per Site	year 1	year 2-? per Site
10	1%	2%	7%	5%	12%	10%	6%	3%	0%	0%
20	1%	3%	13%	9%	23%	20%	13%	5%	1%	1%
40	2%	6%	26%	18%	46%	40%	25%	10%	2%	2%
60	3%	9%	39%	28%	68%	59%	38%	15%	3%	3%

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Example #2: Calculate Hourly Rates to Apply to sIRB Activities
Vanderbilt University

Charges for Primary Activities:

1. Calculate an average rate per activity (initial review full board, initial review expedited, major amendment, minor amendment, continuing review full board, continuing review expedited).
2. Create time studies to calculate effort for each activity (e.g., pre-review and review time for initial review, continuing review, amendments, etc.).
3. Calculate an hourly rate based on time spent and salary of the individual performing the activity.
4. Apply the hourly rate to each activity.
5. Charge each activity based on hourly rate (e.g., initial review takes XX amount of time = set rate for activity).
6. The above steps set your fee schedule.

Charges for Secondary Activities

These can follow the same pathway as above, however the activity and time spent will be greatly reduced, allowing a per-site fee for each individual activity. It is important to save the data to support your charges for federal cost accounting purposes. Figure 6 below demonstrates two examples of calculating sIRB costs for Secondary Activities using this model.

FIGURE 6: CALCULATING PERCENT EFFORT

Time Study "A" Assumptions:
The project includes an average of 10-15 sites
The sIRB institution is not the Prime Awardee
The sIRB institution is the IRB of Record
No pre-existing reliance agreements

sIRB RELIANCE AGREEMENT SET UP	STAFF TIME/HOURS
Drafting of reliance	2
Negotiating reliance	16
Signatures	1
TOTAL	**19**
LOCAL CONTEXT	
Gathering local context from sites	8
Consent form development based on local context	10
Approval letter development	2
Consent form stamping	10
TOTAL	**30**
POST MEETING	
Notification to all sites of approval	4
TOTAL	**4**
REVIEW AND REPORTING (EXTERNAL SITES)	
Review of reportable events	1
Review of noncompliance	1
Review of complaints	6
Reporting to federal agencies	2
TOTAL	**10**

Time Study "B" Assumptions:
The project includes an average of 10-15 sites
The sIRB institution is not the Prime Awardee
The sIRB institution is the IRB of Record
Existing reliance agreement

sIRB RELIANCE AGREEMENT SET UP	STAFF TIME/HOURS
Drafting of reliance	0
Negotiating reliance	0
Signatures	0
TOTAL	**0**
LOCAL CONTEXT	
Gathering local context from sites	8
Consent form development based on local context	10
Approval letter development	2
Consent form stamping	10
TOTAL	**30**
POST MEETING	
Notification to all sites of approval	4
TOTAL	**4**
REVIEW AND REPORTING (EXTERNAL SITES)	
Review of reportable events	1
Review of noncompliance	1
Review of complaints	6
Reporting to federal agencies	2
TOTAL	**10**

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Example #3: Calculate Hourly Rates to Apply to sIRB Activities
Boston Children's Hospital

This model uses the following steps to create a cost for projects based on personnel costs:

1. Determine the amount of time it takes to accomplish specific tasks that reflect the extra work required when acting as an sIRB.
2. Determine the rate to be charged for each staff person's time to create a cost per person for each task.
3. Using the rate spreadsheets, an IRB Office staff member meets with the PI of the study to review the proposed budget for their project.

FIGURE 7: EXAMPLE RATE SCHEDULES

One-Time Activites per Project:

- Pre-implementation phone call
- Review of site information sheet
- Review of proposed budget
- Package forms for sites
- Email sites

All costs and salary data are ***examples*** *and do not reflect actual salaries or rates.*

PERSONNEL	EFFORT (HOURS)	SALARY PER HOUR	TOTAL COSTS
Up to 10 Sites			
IRB Reliance Analyst	2.5	$50	$125
IRB Director	1.0	$100	$100
TOTAL			**$225**
Over 10 Sites			
IRB Reliance Analyst	4.0	$50	$200
IRB Director	2.0	$100	$200
TOTAL			**$400**

Per-Site Discussions and Activities

PERSONNEL	EFFORT (HOURS)	SALARY PER HOUR	TOTAL COSTS
New Reliance Agreement			
IRB Reliance Analyst	4.0	$50	$200
IRB Director	2.0	$100	$200
Attorney	2.0	$150	$300
TOTAL			**$700**
SMART IRB or PedsNet Agreement			
IRB Reliance Analyst	2.0	$50	$100
TOTAL			**$100**

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Activities when Boston Children's is *not* a performance site and the PI is not at Boston Children's:

- Initial review includes master protocol and master consent and/or assent

All costs and salary data are **examples** *and do not reflect actual salaries or rates.*

PERSONNEL	EFFORT (HOURS)	SALARY PER HOUR	TOTAL COSTS
Pre-Review			
IRB Reliance Analyst	4.00	$50	$200
TOTAL			**$200**
Expedited Review (no consent)			
IRB Reliance Analyst	1.00	$50	$50
IRB Chair/Member	0.75	$150	$113
TOTAL			**$163**
Expedited Review (include 1 consent, 1 assent)			
IRB Reliance Analyst	2.50	$50	$150
IRB Chair/Member	1.50	$150	$225
TOTAL			**$375**
Full Review (include 1 consent, 1 assent)			
IRB Reliance Analyst	3.00	$50	$150
IRB 2 Members/Chair	4.00	$150	$600
TOTAL			**$750**
Full Review Response Required Deferral			
IRB Reliance Analyst	2.00	$50	$100
IRB 2 Members/Chair	2.00	$150	$300
TOTAL			**$400**
Full Review Response Required CA IRB Member			
IRB Reliance Analyst	1.50	$50	$75
IRB Chair/Member	1.50	$150	$225
TOTAL			**$300**
Full Review Response Required CA Analyst			
IRB Reliance Analyst	1.50	$50	$75
TOTAL			**$75**
Extra Consents Beyond Initial Consent/Assent			
IRB Reliance Analyst	0.50	$50	$25
TOTAL			**$25**
Continuing Review – Expedited			
IRB Reliance Analyst	2.00	$50	$100
IRB Chair/Member	1.00	$150	$150
TOTAL			**$250**
Continuing Review – Full Review with Response Required on 25%			
IRB Reliance Analyst	3.00	$50	$150
IRB Chair/Member	1.50	$150	$225
TOTAL			**$375**

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Example Relying Site per-Site Costs when Boston Children's is a Performance Site with a Boston Children's PI:

All costs and salary data are ***examples*** *and do not reflect actual salaries or rates.*

PERSONNEL	EFFORT (HOURS)	SALARY PER HOUR	ACTIVITY COST	TOTAL COSTS
No IRB Review Needed (no consent/no assent)				**$100**
IRB Reliance Analyst	2.00	$50	$100	
No IRB Review Needed (consent/assent)				**$125**
IRB Reliance Analyst	2.50	$50	$125	
IRB Review (include 1 consent, 1 assent)				**$300**
IRB Reliance Analyst	3.00	$50	$150	
IRB Chair/Member	1.00	$150	$150	
Full Review (include 1 consent, 1 assent)				**$750**
IRB Reliance Analyst	3.00	$50	$150	
IRB 2 Members/Chair	4.00	$150	$600	
Extra Consents Beyond Initial Consent/Assent				**$25**
IRB Reliance Analyst	0.50	$50	$25	
Continuing Review (includes 1 consent, 1 assent)				**$25**
IRB Reliance Analyst	0.50	$50	$25	
Amendment – Staff Administrative Review (no response required)				**$38**
IRB Reliance Analyst	0.75	$50	$38	
Amendment – Expedited (no consent/assent changes, few require response)				**$188**
IRB Reliance Analyst	1.50	$50	$75	
IRB Chair/Member	0.75	$150	$113	
Amendment – Expedited (with consent/assent changes, 1/2 require response)				**$250**
IRB Reliance Analyst	2.00	$50	$100	
IRB Chair/Member	1.00	$150	$150	
Amendment – Full Review (no consent/assent changes, 1/3 no response, 1/3 expedited response, 1/3 full review response)				**$188**
IRB Reliance Analyst	1.50	$50	$75	
IRB Chair/Member	0.75	$150	$113	
Amendment – Full Review (with consent/assent changes, 1/3 no response, 1/3 expedited response, 1/3 full review response)				**$425**
IRB Reliance Analyst	2.50	$50	$125	
IRB Chair/Member	2.00	$150	$300	

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FIGURE 8: EXAMPLE sIRB BUDGET WORKSHEET FOR USE IN CONSULTATION WITH PI

Reliance and Organization Costs			
	SITES	**AMOUNT**	**TOTAL**
Pre-implementation <10 sites			$
Pre-implementation >10 sites			$
New Reliance Agreement			$
SMART IRB or Peds master			$

Protocol Review: Applicable only if there is no BCH PI and BCH is not a Performance Site			
	SITES	**AMOUNT**	**TOTAL**
Pre Review (Protocol)			$
Expedited (No Consent)			$
Expedited (include 1 consent, 1 assent)			$
Full Review (1 consent, 1 assent)			$
Additional consents beyond initial consent/assent			$

Adding Reliance Site (Per site — Includes consent/assent preparation for each site)			
	SITES	**AMOUNT**	**TOTAL**
No IRB review needed (no consent)			$
No IRB review needed (consent/assent)			$
IRB review needed (consent/assent)			$
Additional consent/assent			$

Continuing Review: Applicable only if there is no BCH PI and BCH is not a Performance site			
	SITES	**AMOUNT**	**TOTAL**
Expedited			$
Full Review			$

Continuing Review			
	SITES	**AMOUNT**	**TOTAL**
Per Relying Site (1 consent/1 assent)			$
Additional consent/assent			$

Amendments			
When there is no BCH PI, and BCH is not a Performance Site **or** *A Site-specific Amendment is submitted when a BCH PI, and BCH is a Performance Site*			
	SITES	**AMOUNT**	**TOTAL**
Administrative review by staff			$
Expedited (no consent)			$
Expedited (with consent/assent changes)			$

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Full Review (no consent/assent changes)			$
Full Review (with consent/assent changes)			$
When BCH PI submits an amendment that changes relying site consents			
Each additional consent/assent changes			$

Unanticipated Problems			
When there is no BCH PI, and BCH is not a performance site or site-specific UAP			
	SITES	**AMOUNT**	**TOTAL**
Administrative Review			$
Full Review			$
Reportable Event in addition to full review cost			$
		GRAND TOTAL	$

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Example #4: Use of Weighting & Variance Factors in Current- and Future-State Costing Models
Washington University in St. Louis

**The WU Costing Model is under development as a publicly available web-based tool with funding from an NCATS Administrative Supplement for "Development of Resources to Facilitate Single IRB Review for Multi-Site Research" (NOT-TR-17-018).*

This approach uses three basic steps to create a fee schedule as well as an efficient grant or project budgeting tool:

1. Determine cost/form to run the IRB and IRB office (effort-based costs).
2. Determine weighting and variance factors that, in a future state, may impact workload and staffing needs.
3. Apply costing model to create a grant or project budget.

1. Determining Costs/Form Processed

This step requires collecting financial information that is typically already tracked and reviewed on a periodic basis within an organization and would normally be available during an annual budgeting cycle.

a. Determine the actual costs for one fiscal year of the IRB and administrative unit (IRB office) that supports the IRB activities. This should include both personnel and other expenses needed to support the entire operation of the office.

b. Determine the total number of staff in the IRB office (for all activities). This should be calculated as Full-Time Equivalents (FTEs) and may include partial FTEs if staff are part-time or if full-time staff have shared responsibilities with other units (e.g., a staff member at .50 FTE with the IRB office and .50 FTE with animal research office would only contribute .50 to the overall FTE for the IRB office.)

c. Count the number of each type of form processed in a fiscal year. Identify the form types or application units that are processed by the IRB office and reviewed by the IRB that you would like to account and charge fees for in your costing model. Each IRB office may name these units differently or combine them in different ways, however an example count may look like the table in Figure 9.

FIGURE 9: COUNTING NUMBER OF FORMS BY TYPE PROCESSED IN A FISCAL YEAR

All numbers are ***examples*** *and do not reflect actual numbers of forms.*

FORM TYPE	TOTAL NUMBER OF FORMS PROCESSED IN FISCAL YEAR
New	1,700
Modification/Amendment	8,000
Combined Modification/Continuing Review	2,000
Continuing Review/Closure	4,000

**To maintain a simplified model and for reasons discussed earlier in this document, this example does not include reportable events or exceptions/deviations.*

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2. Weighting and Variance Factors – See Figures 10 and 11

a. To create the weighting for each form type, we:

i. Identified the number of forms by type processed by the IRB office staff on average in a week's time.

ii. Calculated the number of staff hours per week based on the number of staff.

iii. Using these two values we developed a weight for each form relative to the differences in time it takes to process each form type. For example, a new project may take three times longer to process than a modification.

b. Variance factors were identified based on our experience as an sIRB, as well as discussions with peer institutions related to factors impacting IRB staff and committee efforts regarding sIRB activities. We included in the model a number of variance factors, each of which may be independently adjusted by altering the percentages of our study portfolio and weighting each factor in terms of required effort. These variances are created for both our current state and future state. As we adjust for future state, the number of staff needed are increased or decreased, which is reflected in the table that calculates cost per form.

Variance factors:

- Domestic versus international site
- Academic versus non-academic site (or research experienced/research naïve, e.g., community sites)
- Established reliance agreement versus not having an existing reliance agreement
- Number of sites (<10 vs >10; assumes work does not increase in a linear manner as number of sites increases)
- Percentage of sites with same state laws

FIGURE 10: USING WEIGHTING TO DISTRIBUTE TOTAL COSTS ACROSS FORM TYPES

All costs and data are ***examples*** *and do not reflect actual information.*

		Project Forms + Refs	Project Forms Only		**Summary**	
						Current-All Studies
3	Campus 1	16,188	15,245		Total $ cost	$ 2,250,000
4	Campus 2	1,542	1,479		$/Form	$ 135
5	Total	17,730	16,724		FTE	18.00
6					Total Forms	16,724
7		*Select relative weight 1 - 12 scale (12 being most difficult)*				
8						
9	All types of funding				All Studies	
10	WUSTL - wide	New	Mod	Mod/CR	CR	
11	*Level*	12	2	2	1	17
12	Total $ cost	$ 1,588,235.29	$ 264,705.88	$ 264,705.88	$ 132,352.94	$ 2,250,000
13	$/Form	$ 911.21	$ 26.75	$ 115.14	$ 47.47	$ 134.54
14	FTE	12.71	2.12	2.12	1.06	18.00
15	Full Board	517	616	724	240	
16	Expedited/Exempt	1,185	8,703	1,561	2,516	
17	sIRB (defer)	41	322			
18	Withdrawn		253	14	32	
19					16,724	**$ 2,250,000**
20	**FTE**	18				

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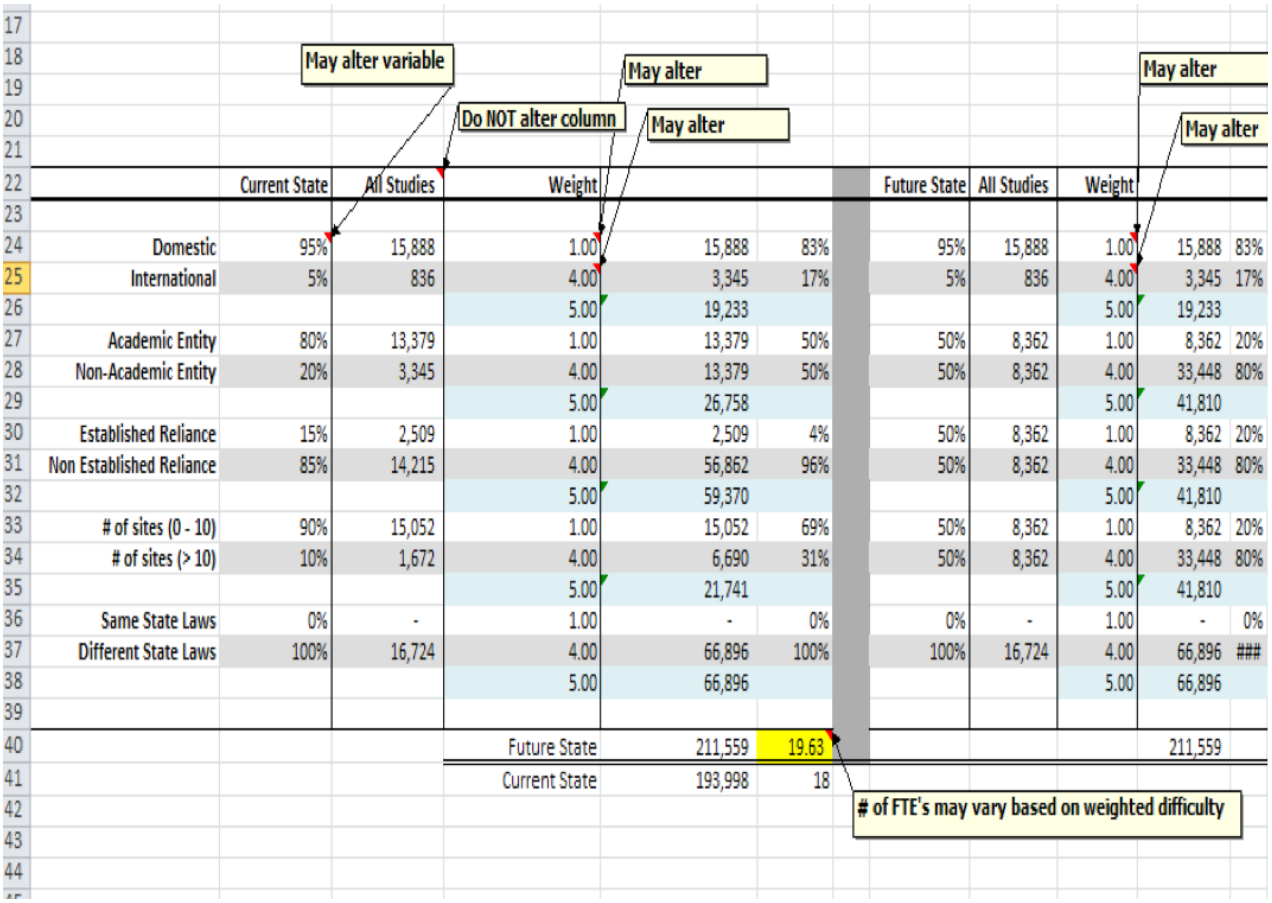
FIGURE 11: WEIGHTED VARIANCE FACTORS

All data are **examples** *and do not reflect actual information.*



	Current State	All Studies	Weight			Future State	All Studies	Weight		
Domestic	95%	15,888	1.00	15,888	83%	95%	15,888	1.00	15,888	83%
International	5%	836	4.00	3,345	17%	5%	836	4.00	3,345	17%
			5.00	19,233				5.00	19,233	
Academic Entity	80%	13,379	1.00	13,379	50%	50%	8,362	1.00	8,362	20%
Non-Academic Entity	20%	3,345	4.00	13,379	50%	50%	8,362	4.00	33,448	80%
			5.00	26,758				5.00	41,810	
Established Reliance	15%	2,509	1.00	2,509	4%	50%	8,362	1.00	8,362	20%
Non Established Reliance	85%	14,215	4.00	56,862	96%	50%	8,362	4.00	33,448	80%
			5.00	59,370				5.00	41,810	
# of sites (0 - 10)	90%	15,052	1.00	15,052	69%	50%	8,362	1.00	8,362	20%
# of sites (> 10)	10%	1,672	4.00	6,690	31%	50%	8,362	4.00	33,448	80%
			5.00	21,741				5.00	41,810	
Same State Laws	0%	-	1.00	-	0%	0%	-	1.00	-	0%
Different State Laws	100%	16,724	4.00	66,896	100%	100%	16,724	4.00	66,896	###
			5.00	66,896				5.00	66,896	
			Future State	211,559	19.63				211,559	
			Current State	193,998	18					

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3. Application to create a grant or project budget

The cost per form determined by the previous steps feeds the Grant (Project) Budgeting Tool. The example below shows the tool with the following factors which may be altered as needed:

a. Uses a five-year grant period (or appropriate period)

b. Identifies the total number of each type of form that would require review over the grant/project period at one site

1	New form (to initiate a site)
6	Modifications (based on average number of modifications for a federally-funded study at WU from approval to closure)
4	Continuing reviews
1	Closure (counted in with continuing review forms)
12	Forms (total) for one site (agrees with average number of actual forms for a federally-funded study at WU from open to close)

c. Multiply the total number of forms by type, by number of sites, and cost per form (may include sIRB site, depending on their role in the study and factors discussed in PTC#1). See Figure 12.

FIGURE 12: SIRB BUDGET FOR 10 AND 5 SITES FOR A 5-YEAR GRANT PROPOSAL

All costs and data are **examples** *and do not reflect actual salaries or rates.*

Grant Budgeting Tool	Total Sites	10	
sIRB Forms	Forms/study/site	Total Forms	Total Cost
New	1	10	$ 10,235
Mod	6	60	$ 1,803
Mod/CR	2	20	$ 2,587
CR/Close	3	30	$ 1,600
Total	12	120	$ 16,224

Grant Budgeting Tool	Total Sites	5	
sIRB Forms	Forms/study/site	Total Forms	Total Cost
New	1	5	$ 5,117
Mod	6	30	$ 902
Mod/CR	2	10	$ 1,293
CR/Close	3	15	$ 800
Total	12	60	$ 8,112

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CONTRIBUTING AUTHORS

Jeri Burr, MS, RN-BC, CCRC, FACRP
Executive Director
Trial Innovation Center | University of Utah

Nate Buscher
Program Management Officer
University of California Biomedical Research Acceleration, Integration, & Development (UC BRAID)

Michelle Culp, BSN, MPH
Director of Clinical Operations, Division of Clinical Innovation
National Center for Advancing Translational Science, National Institutes of Health

Valery Gordon, PhD, MPH
Senior Advisor, Human Subjects Protection
Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health

Martha F. Jones, MA, CIP
Executive Director, Human Research Protection Office
Washington University in St. Louis

Susan Kornetsky, MPH
Senior Director Clinical Research Compliance
Boston Children's Hospital

Michael Linke, PhD, CIP
Health Science Officer, Department of Veterans Affairs Medical Center-Cincinnati
Associate Professor, University of Cincinnati College of Medicine
Chair, University of Cincinnati Institutional Review Board

Julie Ozier, MHL, CHRC, CIP
Director, Human Research Protection Program
Vanderbilt University and Vanderbilt University Medical Center

Judith Spilker, RN, BSN
Administrative Director
NIH StrokeNet, University of Cincinnati

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SMART IRB HARMONIZATION STEERING COMMITTEE LEADERSHIP

Barbara E. Bierer, MD
Director of Regulatory Policy, SMART IRB
Co-chair, SMART IRB Harmonization Steering Committee

Valery Gordon, PhD, MPH
Senior Advisor, Human Subjects Protection, Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health
Co-chair, SMART IRB Harmonization Steering Committee

Aaron Kirby, MSc
Director, Regulatory Affairs Operations, Harvard Catalyst
Operations Officer, SMART IRB Harmonization Steering Committee

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RESOURCES

CCTST Regulatory Forum Single IRBs for multisite studies: costs to consider, May 25, 2017 https://cctst.uc.edu/node/3109

Cost Accounting Standards Board Disclosure Statement Required by Public Law 100-679 Educational Institutions, Name of Reporting Unit: University of Utah, Salt Lake City, Utah, Revision Number 1, Effective date September, 20, 2006

Council on Government Relations – February 23, 2017 NIH Single IRB Policy: Costing Perspective http://www.cogr.edu/sites/default/files/NIH%20Session%20on%20the%20Single%20IRB%20Policy_022317.pdf

Council on Government Relations - Meeting Washington Marriott Hotel Washington, DC, February 23, 2017, Independent/commercial IRB http://www.cogr.edu/sites/default/files/Implementation%20of%20the%20NIH%20Single%20IRB%20Policy_COGR%20Institutions_022317.pdf

Hockberger P, Meyn S, Nicklin C, Tabarini D, Turpen P, Auger J. Best Practices for Core Facilities: Handling External Customers. Journal of Biomolecular Techniques : JBT. 2013;24(2):87-97.

NIH Releases Final Policy on the Use of a Single Institutional Review Board for Multi-Site Research https://osp.od.nih.gov/2016/06/21/nih-releases-final-policy-on-the-use-of-a-single-institutional-review-board-for-multi-site-research/

NIH Policy on the Use of a Single IRB for Multi-Site Research Costs
https://osp.od.nih.gov/clinical-research/nih-policy-on-the-use-of-a-single-irb-for-multi-site-research-faqs-on-costs/

NIH Cost Considerations
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7_cost_consideration.htm

Office of Management and Budget, Circular A-21, Cost Principles for Educational Institutions. Educational institutions (OMB Circular A-2115) and NPOs (OMB Circular A-12216).

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