FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Single Institutional Review Board (sIRB): Implementation and Costing Updates

Michelle Bulls, OPERA – National Institutes of Health

Jim Luther, Duke University

Joe Gindhart, Washington University in St. Louis

Sara Bible, Stanford University

May 11, 2017

Overview

- Implementation Date
- Context and applicability
- Costing FAQs
- Implementation at institutions

Implementation Date

- Extended to September 25, 2017 (NOT-OD-17-027)
  - Effective for applications submitted on or after this date

- Institutions have an additional four months

Context & Applicability

- Applies to:
  - Domestic sites of multi-site studies
  - Each site conducting same protocol involving non-exempt human subjects research

NIH sIRB Costing FAQ #2

2. May direct costs be used to support administrative tasks of supporting an sIRB

1. Direct charges for the salaries of administrative and clerical staff are allowable, but only if all of the following conditions are met:
   (1) administrative or clerical services are integral to a project or activity;
   (2) individuals involved can be specifically identified with the project or activity;
   (3) such costs are explicitly included in the budget; and
   (4) the costs are not also recovered as indirect costs.
   (5) Such charges must also meet the criteria for allowable costs described in 45 CFR 75.403. Under the NIH Standard Terms of Award, these costs do not require NIH prior approval as long as the above conditions and criteria are met, and the recipient has appropriate supporting documentation.

NIH sIRB Costing FAQ #6

6. May recipient institutions develop standard fees for sIRB review costs, and charge these fees to NIH awards as direct costs according to a set schedule (e.g., per site, per year, per event, etc.)?

- Recipient institutions have the flexibility to develop their own fee structures for sIRB costs. Such an arrangement would be considered a specialized service facility and as such must adhere to the requirements of 45 CFR 75.468 as follows:
- (a) The costs of services provided by highly complex or specialized facilities operated by the non-Federal entity, such as computing facilities, wind tunnels, and reactors are allowable, provided the charges for the services meet the conditions of either paragraphs (b) or (c) of this section, and, in addition, take into account any items of income or Federal financing that qualify as applicable credits under §75.406.

NIH sIRB Costing FAQ #6

- (b) The costs of such services, when material, must be charged directly
- to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology that:
- (1) Does not discriminate between activities under Federal awards and other activities of the non-Federal entity, including usage by the non-Federal entity for internal purposes, and
- (2) Is designed to recover only the aggregate costs of the services. The costs of each service must consist normally of both its direct costs and its allocable share of all indirect (F&A) costs. Rates must be adjusted at least biennially, and must take into consideration over/under applied costs of the previous period(s).
- (c) Where the costs incurred for a service are not material, they may be allocated as indirect (F&A) costs.
- (d) Under some extraordinary circumstances, where it is in the best interest of the Federal Government and the non-Federal entity to establish alternative costing arrangements, such arrangements may be worked out with the Federal cognizant agency for indirect costs.

Costing Guidance

- Primary activities:
  - Activities associated with conducting the ethical review of the proposed research protocol and the review of the template informed consent document.
- Secondary activities:
  - Activities associated with the review of site specific considerations (unlike circumstances) for all of the participating sites.

Costing Guidance

- Policy does not require sIRB costs to be direct charged.
  - Institutions retain flexibility in deciding how they will assign costs.

- Cost Allocation Services (CAS) supports guidance provided re: distinction between primary & secondary costs (NOT-OD-16-109)

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?

Washington University in St. Louis
Data and Calculations - Draft

- **IRB YTD/Operational Expenses & FTEs**
- **IRB Form Type & YTD Form Count**
- **Work Time per Form *Derives* Weight/Complexity**
- **Fee/Cost Per Form Calculation**
- **Forms Per Site * Fee Per Form = Per Site Fees**
- **Per Site Fees * Number of Sites = Budget for sIRB**

IRB Staffing and FTEs

Operations

Manager, IRB Review
IRB Review Analyst
IRB Review Analyst
IRB Review Analyst
Sr. IRB Review Analyst
Expedit. Review Specialist
Protocol Specialist

Operations (7 FTEs)

Strategic

Director, IRB
Education Specialist
eIRB System Specialist
Project Specialist
Scheduler

Strategic (5 FTEs)

IRB YTD Expenses & FTEs

Sample numbers: these numbers do not represent the IRB costs of WUSTL

Expense Category	Total YTD Exp	Operations Only
Salaries	$ 688,000	$ 355,000
Benefits	137,600	71,000
Consultants	12,000	7,000
Supplies	18,000	10,500
Travel	51,000	29,750
Other Expenses	79,000	46,083
Total Expense	985,600	519,333
FTEs	12	7
Per FTE Expense	$ 82,133	$ 74,190

IRB Form Type and Counts

Sample numbers: these numbers do not represent the IRB costs of WUSTL

Form Type	New	Mod	Mod/CR	CR	Total
Full Board	425	515	670	340	1,950
Expedited	1,085	6,700	1,200	1,900	10,885
sIRB (defer)	30	200			230
Withdrawn		175	15	35	225
Totals	1,540	7,590	1,885	2,275	13,290

sIRB Activities

- **Initial Site Review**: Reliance/joinder agreement negotiations, local context review and preparation of local IRB approval, consent, or other local documents, review of site's proposed conduct of the study, liaison activities with local HRPP

- **Protocol Modification**: Review/approve documentation when a study-wide or local modification is required

sIRB Activities, cont.

- **Continuing Review: Review of local site progress report, preparation of approval documentation for each participating site**
- **Site Closure: Process closure information and liaison activities with local site and local HRPP to ensure proper closure of study activities**

Worktime & Weight

sIRB Activity	Work Time (hrs)		Weight/ Complexity
New Protocol Review	5	→	10
Initial Site Review	5	→	10
Protocol Modification	2	→	4
Mod. & Cont. Review	3	→	6
Continuing Review	1	→	2

Per Form Cost/Fee Calculations

Sample numbers: these numbers do not represent the IRB costs of WUSTL

Form Type	New	Mod	Mod/CR	CR	Total
Weight/Complexity	10	4	6	2	22
Total $ cost	$ 448,000	$ 179,200	$ 268,800	$ 89,600	$ 985,600
$/Form	$ 291	$ 24	$ 143	$ 39	$ 74
FTE	5.45	2.18	3.27	1.09	12.00
Full Board	425	515	670	340	
Expedited/Exempt	1,085	6,700	1,200	1,900	
sIRB (defer)	30	200			
Withdrawn		175	15	35	
Totals	1,540	7,590	1,885	2,275	$ 985,600
FTE	12.00				13,290

Forms Per Site & Fees

Sample numbers: these numbers do not represent the IRB costs of WUSTL

sIRB Activity	Weight/ Complexity	Estimated Forms	Per Form Fee	Total
Initial Site Review	10	1	$ 291	$ 291
Protocol Modification	4	6	24	144
Continuing Review	2	4	39	156
Site Closure	2	1	39	39
Total Per Site		12		$ 630

sIRB Fees for Project Budget

Sample numbers: these numbers do not represent the IRB costs of WUSTL

sIRB Activity	Year 01	Year 02	Year 03	Year 04	Year 05	Total
Initial Site Review	$ 291					$ 291
Protocol Mod.	48	24	24	24	24	144
Continuing Review		39	39	39	39	156
Site Closure					39	39
Total Per Site	339	63	63	63	102	630
Sites	6	6	6	6	6	
Total Fees	$2,034	$378	$378	$378	$612	$ 3,780

NIH Resources

SingleIRBpolicy@mail.nih.gov

GrantsCompliance@nih.gov

Implementation FAQs:
http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review

Discussion and Questions