



Session I

Models for Institutions Serving as sIRB of Record

Single IRB Review for Multi-Site Research:
Resource and Infrastructure Development Workshop
September 12, 2018

Washington University in St. Louis

The University of Iowa



Costing Model Tool (CMT)

- Facilitates sIRB activities by providing accurate justifiable “at-cost” fee schedules for institutions providing services as a single IRB
- In support of multi-site research, the fee schedule feeds into a grant budget builder that automates generation of budgets for grant applications
- Accessible and generalizable to any institution
- Model for common approach to fees across SMART IRB institutions

Costing Model Tool (CMT)

Current Model: CMT for sIRB Workshop

FTEs

Number of FTEs	Total Expenditure
15.0	\$575,000

Forms

Form Type	Full Board		
	Count	DF	
New	200	8	✗
Mod	350	7	✗
CR	300	4	✗

Conditional elements

Condition	Percentage	Form Total	Weight	
Domestic	90%	765.0	1.0	✗
International	10%	85.0	4.0	
Community Partners	10%	85.0	0.0	✗
Academic Researchers	90%	765.0	0.0	

Cost Per Form

Form Type	Full Board
New	\$1,211
Mod	\$605
CR	\$404

Future Model

FTEs

Number of FTEs	Total Expenditure
28.8	\$1,105,769

Forms

Form Type	Full Board	
	Count	DF
New	200	8
Mod	350	7
CR	300	4

Conditional elements

Condition	Percentage	Form Total	Weight
Domestic	50%	425.0	1.0
International	50%	425.0	4.0
Community Partners	10%	85.0	0.0
Academic Researchers	90%	765.0	0.0

Cost Per Form

Form Type	Full Board
New	\$2,328
Mod	\$1,164
CR	\$776

Costing Model Tool (CMT)

Costing Model: **CMT for SIRB Workshop**

Name of Budget: NIH 5-year Budget

Number of Sites: 10

Number of Years: 5 (Maximum: 20)

Annual Inflation Factor: 3 %

Forms to include in the Budget

Form Type	# of forms per site each year	years to app.	Total Forms	Total Cost	
New	1	1	10	\$12,110	X
Mod	3	all	30	\$18,150	X
CR	1	all	10	\$4,040	X
Total	5		50	\$34,300	

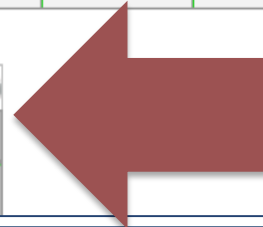
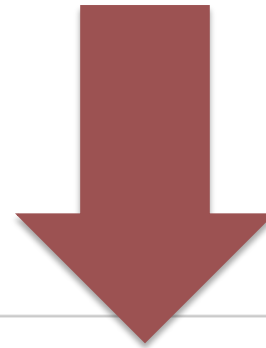


Budget Totals

Form Type	Cost/Form	Year 1 Forms	Year 1 Cost	Year 2 Forms	Year 2 Cost	Year 3 Forms	Year 3 Cost	Year 4 Forms	Year 4 Cost	Year 5 Forms	Year 5 Cost
New	\$1,211	1	\$1,211	0	\$0	0	\$0	0	\$0	0	\$0
Mod	\$605	3	\$1,815	3	\$1,869	3	\$1,925	3	\$1,983	3	\$2,042
CR	\$404	1	\$404	1	\$416	1	\$428	1	\$441	1	\$454
Total		5	\$3,430	4	\$2,285	4	\$2,353	4	\$2,424	4	\$2,496

Grand Totals

Cost/Site	Total Cost
\$12,988	\$129,880



Responsibility Matrix Tool (RMT)

- Facilitates sIRB activities and multi-site research by displaying a table for each study of the responsibilities of the sIRB, the relying institutions, the PIs and other key components such as a coordinating or data center.
- Supports SMART IRB through a built-in template that documents the fixed terms in the SMART IRB reliance agreement and allows customization of the flexible terms on a study-by-study or consortium basis
- Accessible and generalizable to any institution and all participating sites and PIs in the multi-site research

Responsibility Matrix Tool (RMT)

Responsibility Matrix for Study ID: 201809150

Title: sIRB Workshop
Reviewing IRB: Washington University in St. Louis
Principal Investigator: John Doe

201809150

Attachment Name	Comments	Ver	Size	Attached
SMART_IRB_Agreement.pdf		1	446 k	09/07/18 delete edit

To edit or version attachments, use the edit link above.

[Upload file\(s\)](#)

Template: sIRB Workshop - SMARTIRB Template

Category	Term	Lead PI	Reviewing IRB	Relying Institution	Site PI	Other
Notifications	Notify of Acceptance or Declination of Ceded Review		X			
Notifications	Notify of IRB Determinations	X	X			
Notifications	Notify IRB of UPIRTSO	X Within 10 days of receipt.				
Standard Operating Procedures (SOPs)	SOPS to be followed for this study Provide link or location of SOPs University of Northern New Jersey IRB SOPs. irb.unnj.edu		X			
Standard Operating Procedures (SOPs)	Conduct Initial and Continuing IRB Review and review of Modifications		X			
Consent Forms	Provide local and institutionally required language			X		
Consent Forms	Provide approved consent forms		X			
Local Context	Provide local context review information			X		
Local Context	Ensure research team has appropriate training and qualifications			X		
Local Context	Conduct all ancillary reviews			X		
				X		



Responsibility Matrix Tool (RMT)

Template:

sIRB Workshop - SMARTIRB Template

Category	Term	Lead PI	Reviewing IRB	Relying Institution	Site PI
Notifications	Notify of Acceptance or Declination of Ceded Review		X		
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Standard Operating Procedures (SOPs)	Conduct Initial and Continuing IRB Review and review of Modifications		X		
Consent Forms	Provide local and institutionally required language			X	
Consent Forms	Provide approved consent forms		X		
Local Context	Provide local context review information			X	
Local Context	Ensure research team has appropriate training and qualifications			X	

Responsibility Matrix Tool (RMT)

RMT Administrator Matrix:

Category	Term	Reviewing IRB	Relying Institution	Coordinating Center	Lead PI	Site PI	Site Staff	Other	
Notifications	Notify Coordinating Center of any subject death					X Notify within 24 hours of death	X Notify within 24 hours of death		Edit Delete



PI Matrix:

Category	Term	Reviewing IRB	Relying Institution	Coordinating Center	Lead PI	Site PI	Site Staff	Other	
Delegation log	Responsible for updating Delegation Log						X Lead Coordinator		Edit Delete



Project Management Tool (PMT)

- Facilitates multi-site research by providing a tool to document and track the wide variety of study and site level activities necessary for study start-up
 - Provides transparency of site status
 - Provides single place for documentation of key information with customizable reminders when documents must be renewed over the course of a study
- Facilitates sIRB review by tracking completion of reliance agreements or other key documents
- Addresses common challenge of study start-up
- Accessible and generalizable to any institution



Project Management Tool (PMT)

Best Study Ever

Edit

Export

Archive Study

Access

Study Start Up

CT.gov Registration

Site 1

Not Registered

IRB: 2/2

Contracts: 2/2

Site Docs Clinical: 3/3

Site 2

Not Registered

IRB: 2/2

Contracts: 2/2

Site Docs Clinical: 3/3

Site 3

Not Registered

Edit

Contacts

Archive Site

Access

IRB

Reliance Agreement

IRB Approval of Mod

Contracts

CDA

Contract Executed

Site Docs Clinical

CVs

HSR Training

Signature Page

Clinical Researchers

Site 4

Not Registered

Edit

Contacts

Archive Site

Access

IRB

Reliance Agreement

IRB Approval of Mod

Contracts

CDA

Contract Executed

Site Docs Clinical

CVs

HSR Training

Signature Page

Clinical Researchers

Site 5

Not Registered

IRB: 0/2

Contracts: 0/2

Site Docs Clinical: 0/3

Project Management Tool (PMT)

Project Management Tool

Project Dashboard

▶ Liaison Test

Started: 2

Not Started: 1

▶ PMT Example - sIRB Supplement

Started: 1

Not Started: 2

▶ Best Study Ever

Done: 4

Started: 10

Not Started: 6



Permission Based Access to Tools

- Permissions and access to the tools are granted on a per role basis for the Costing Model and Responsibility Matrix
- Permissions and access are granted by the Coordinating Center to allow site specific tracking of Project Management Tool responsibilities.



	CMT	RMT	PMT
Impact on facilitating sIRB review	✓	✓	✓
Facilitates SMART IRB	✓	✓	✓
Best practices or challenges identified to sIRB facilitation	✓	✓	✓
Generalizable to other institutions	✓	✓	✓



Leadership



WU PI
Dr. Brad Evanoff



Iowa PI
Dr. Jess Fiedorowicz



WU
Dr. Suresh Vedantham



Iowa
Dr. Patricia Winokur

Advisors



WU Co-Chair
Dr. Jonathan
Green



Iowa Co-Chair
Dr. J. Andrew
Bertolatus



Iowa
Dixie Ecklund



Quorum Review IRB
Dr. Stephen
Rosenfeld



WU
Andwele Jolly



WU
Joe Gindhart



The University of Iowa
Michele Countryman,
Michael Kane



Washington University
Christine Lee-Urcia, Abby Turner,
Quinn Yancey, Martha Jones, Amy Carmen,
Carissa Minder, Jeanne Velders



WU
Carla Pinkston



WU
Jamie Stagner



WU
Kiana Wilhite

WU – Not pictured
Jennifer Harlow



**Washington University
in St. Louis**

Patricia Nieters
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Angela Oliver
Kathy Taylor
Michelle Jenkerson
Heather Wilkins

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Kelly Monroe
Kaitlin Moore
Kelly Reske
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**The University
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Heena Olalde
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Gail Ardery