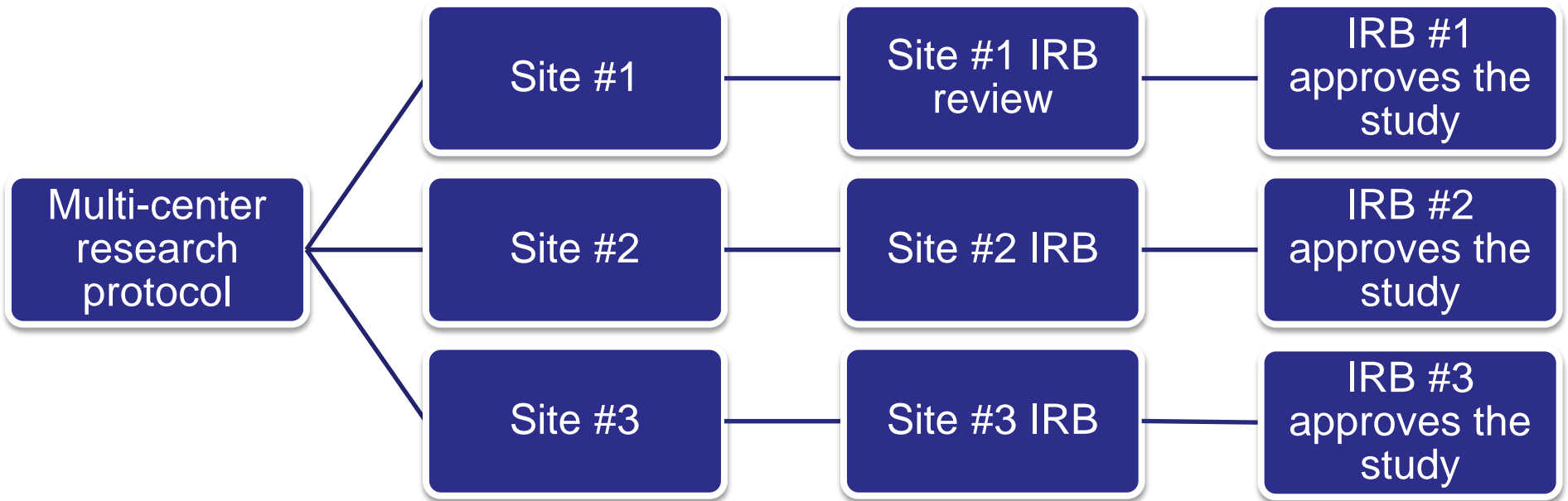


# **Preparing Single IRB Grant Submissions Utilizing the RSRB as the Reviewing IRB**

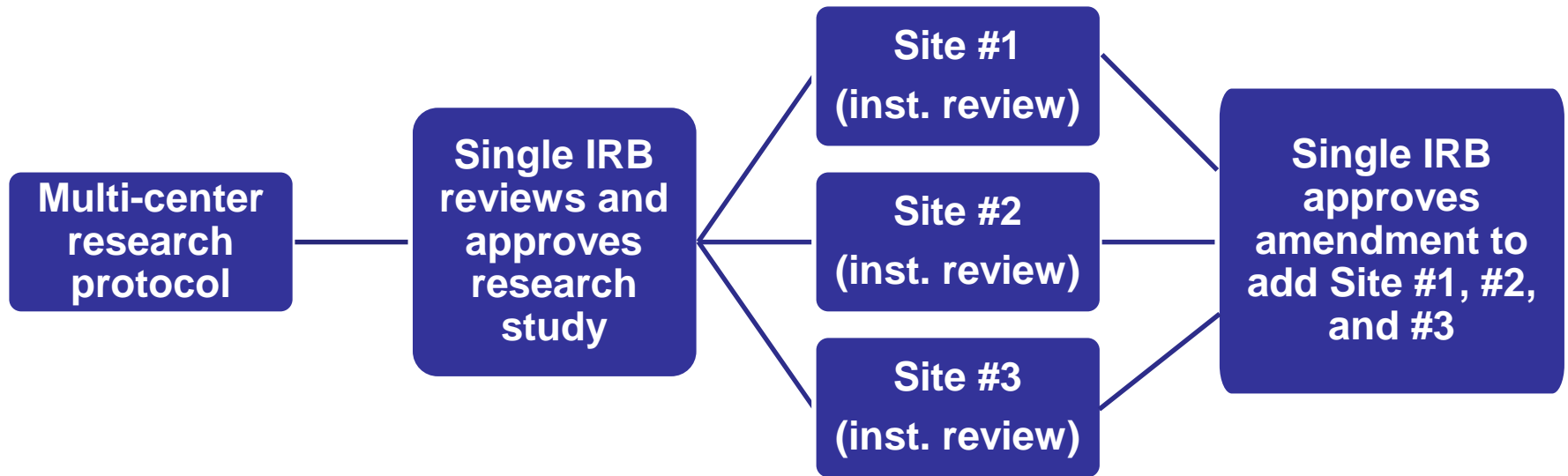
*Tiffany Gommel  
Executive Director, RSRB  
October 4<sup>th</sup> 2017*



# Multiple IRBs Review a Multi-Center Study



# Single IRB Review of a Multi-Center Study



# NIH Final Policy: Single IRB (sIRB) Review for Multi-Site Research

## **Purpose:**

*“To enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.”*



# Definitions

- Single IRB (sIRB) = Central IRB = Reviewing IRB
- Reviewing IRB – The Institutional Review Board (IRB) designated to review and approve human subject research.
- Relying IRB – The Institutional Review Board (IRB) that delegates the responsibility of IRB review and approval to another IRB.

*OHSP Policy 504 - RSRB Reliance for Review*



# Scope of the Policy

- NIH-funded, non-exempt research
- Grant submissions on/after **09/25/2017**
- **Two or more *domestic sites*** conducting the same protocol
  - same research questions, involve the same methodologies, and evaluate the same outcomes
  - accruing research subjects for studies that are identical except for variations due to local context consideration
  - Talk to your Program Officer



# Planning for your Grant Submission & Budgeting



# sIRB Budget and Budget Justification

1		<b>Number</b>				
2	Sites					
3	Expected consent documents					
4	Years for the grant					
5	Years with active study conduct					
6	Protocol only amendments					
7	Recruitment only amendments					
8	Consent form only amendments					
9	Protocol and consent form amendments					
10						
11	<b>Initial</b>	<b>Total costs</b>	<b>Indirect Costs (UR review costs)</b>	<b>Direct Costs (included as line item in budget)</b>	<b>Cost for Review</b>	
12	Primary site initial review (up to 2 consents/site)	\$1,100.00	\$1,100.00		\$1,100.00	
13	Each additional site (up to 2 consents/site)	-\$725.00		-\$725.00	\$725.00	per site
14	Per site per additional consent	\$0.00	-\$200.00	\$200.00	\$100.00	per site per consent
15						
16	<b>Continuing Review</b>				<b>Cost for Review</b>	
17	Primary Site CR review	-\$725.00	-\$725.00		\$725.00	per year
18	Each additional site	\$725.00		\$725.00	\$725.00	per year
19	Close out	\$0.00	\$362.50	-\$362.50	\$362.50	per site
20						
21	<b>Amendment</b>				<b>Cost for Review</b>	
22	Protocol only amendments	\$0.00	\$0.00		\$725.00	per submitted amendment
23	Recruitment only amendments	\$0.00	\$0.00		\$362.50	per submitted amendment
24	Consent form only amendments	\$0.00	\$0.00	\$0.00	\$725.00	per submitted amendment / site
25	Protocol and consent form amendments	\$0.00	\$0.00	\$0.00	\$1,087.50	per submitted amendment / site
26						
27	<b>TOTAL</b>	\$375.00	\$537.50	-\$162.50		
--						





# sIRB Budget and Budget Justification

- Base costs determined from operating budget for FY 2017
  - \$ / review items
  - Determined “work unit cost”
  - Cost for review
    - Determined by work per item
    - Estimate based upon knowledge

<b>Cost for Review</b>	
\$1,100.00	
\$725.00	per site
\$100.00	per site per consent
<b>Cost for Review</b>	
\$725.00	per year
\$725.00	per year
\$362.50	per site
<b>Cost for Review</b>	
\$725.00	per submitted amendment
\$362.50	per submitted amendment
\$725.00	per submitted amendment / site
\$1,087.50	per submitted amendment / site



# sIRB Budget Creation

	Number
Sites	
Expected consent documents	
Years for the grant	
Years with active study conduct	
Protocol only amendments	
Recruitment only amendments	
Consent form only amendments	
Protocol and consent form amendments	

- “Demographic data” needed
  - Sites
  - Expected consent documents
    - ↑ Consent = ↑ Work for the RSRB = ↑ Costs
  - Years for the grant and years for active study conduct
    - Relate to the number of continuing reviews



# sIRB Budget Creation

- “Study Amendment data”
  - Protocol only
    - Single cost/single review
  - Recruitment only
    - Single cost/single review
  - Consent form only
    - Cost per site
  - Protocol and Consent form
    - Cost per site

	Number
Sites	
Expected consent documents	
Years for the grant	
Years with active study conduct	
Protocol only amendments	
Recruitment only amendments	
Consent form only amendments	
Protocol and consent form amendments	

## Use your Best Guesstimate:

1. What experience do you have?  
Colleagues have?
2. What do you know about the population?
3. What do know about this type of study?
4. Review amendments from past similar studies to compare and make an informed guess

Use what you can to make the most informed decision possible!



# What does your information tell you?

- Initial Review

- Breakdown of indirect and direct costs

- Consents = more work

- Consent documents = consent, parent permission, etc.

- Spreadsheet calculates costs

- Accounts for subtracting out indirect costs out of direct

- If less than 2 consent documents, delete “Per site per additional consent” line item

	Initial	Total costs	Indirect Costs (UR review costs)	Direct Costs (included as line item in budget)	Cost for Review	
11						
12	Primary site initial review (up to 2 consents/site)	\$1,100.00	\$1,100.00		\$1,100.00	
13	Each additional site (up to 2 consents/site)	-\$725.00		-\$725.00	\$725.00	per site
14	Per site per additional consent	\$0.00	-\$200.00	\$200.00	\$100.00	per site per consent
15						



# What does your information tell you?

- Continuing Review
  - Breakdown of indirect and direct costs
  - Costs factor in years of study conduct
  - Notice per year and per site

	Total costs	Indirect Costs (UR review costs)	Direct Costs (included as line item in budget)	Cost for Review	
15					
16					
17	-\$725.00	-\$725.00		\$725.00	per year
18	\$725.00		\$725.00	\$725.00	per year
19	\$0.00	\$362.50	-\$362.50	\$362.50	per site
20					



# What does your information tell you?

- Amendment
  - Breakdown of indirect and direct costs
  - Costs factor in number of amendments/type
  - Notice
    - per amendment
    - Per amendment/site

Amendment	Total costs	Indirect Costs (UR review costs)	Direct Costs (included as line item in budget)	Cost for Review	
Protocol only amendments	\$0.00	\$0.00		\$725.00	per submitted amendment
Recruitment only amendments	\$0.00	\$0.00		\$362.50	per submitted amendment
Consent form only amendments	\$0.00	\$0.00	\$0.00	\$725.00	per submitted amendment / site
Protocol and consent form amendments	\$0.00	\$0.00	\$0.00	\$1,087.50	per submitted amendment / site



# Questions



# References

- [NIH Single IRB Policy \(FDP 9/22/2016\)](#)
- [OHSP Policy 504 - RSRB Reliance for Review](#)
- [NIH Final Policy - Single IRB Review for Multi-site research](#)
- [NIH Guidance on sIRB costing](#)
- [NIH Single IRB Policy FAQs for Extramural Community](#)
- [OHSP Presentation on 4/20/2017 – Preparing sIRB Grant Submissions Utilizing the RSRB as the Reviewing IRB](#)

