SRA INTERNATIONAL
ANNUAL MEETING
CHICAGO 2024
OCTOBER 26-30

Single IRB Budget Considerations for Large Federal Grants

A Case Comparison of Independent IRB vs Academic IRB

Introductions

Kellie Hernandez
Distinguished Research Program Manager and Director of CAUSE grant

University of Wisconsin
SCHOOL OF MEDICINE AND PUBLIC HEALTH

Brandy Stoffel, JD, CIP
Education and Research Consulting Senior Associate

HURON

SRA INTERNATIONAL

Objectives

1. Identify indirect costs associated with sIRB logistics for large grants involving multi-site human subjects research.

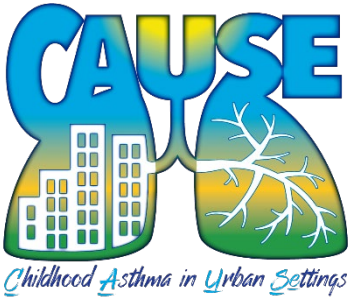
2. Describe three considerations for sIRB selection and analyze participating sites sIRB readiness.

SRA INTERNATIONAL

Agenda

- History of Consortium
- Why Single IRB?
- Pre-Award Decisions
- Metrics
- Anecdotal Challenges

SRA INTERNATIONAL



History of Consortium

Inner City Asthma Consortium (ICAC)

ICAC is a multi-study, multi-center initiative to study the causes of the **urban asthma** epidemic that afflicts millions of children and to develop treatments to improve control of asthma in this population and for children in general.

Childhood Asthma in Urban Settings (CAUSE)

2002 — ICAC formed

NIAID awards $62 million to UW

2009 — ICAC2 awarded

$58.3 million

2014 — ICAC3 awarded

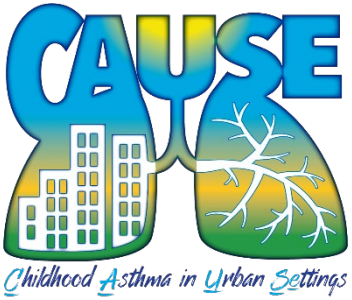
$70 million

2021 — CAUSE awarded

$70 million

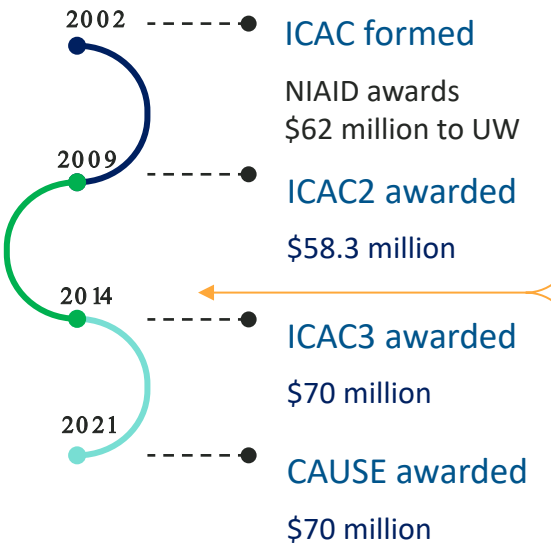
Highlights

- 11 clinical sites
- 6 basic science sites
- Clinical Coordinating Center (Rho)
- Administrative Leadership Center (UW)
- NIH regulatory (DAIT) and medical monitor



Why Single IRB?

Because NIAID said so…

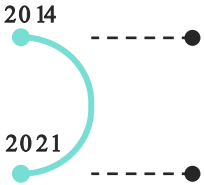


National Institute of Allergy and Infectious Diseases

2013 Funding Opportunity Announcement (FOA) for ICAC3 was issued, utilizing a UM1 Multi-Component Research Project Cooperative Agreement mechanism.

Requirement to "establish a plan for efficient IRB review (within 30 calendar days from submission) and approval for multi-center studies using federated IRB models"

Independent IRB vs Academic IRB



ICAC3 awarded

$70 million

CAUSE awarded

$70 million

Western Copernicus Group

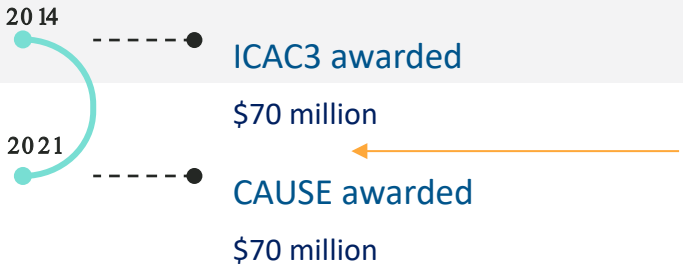
Independent IRB

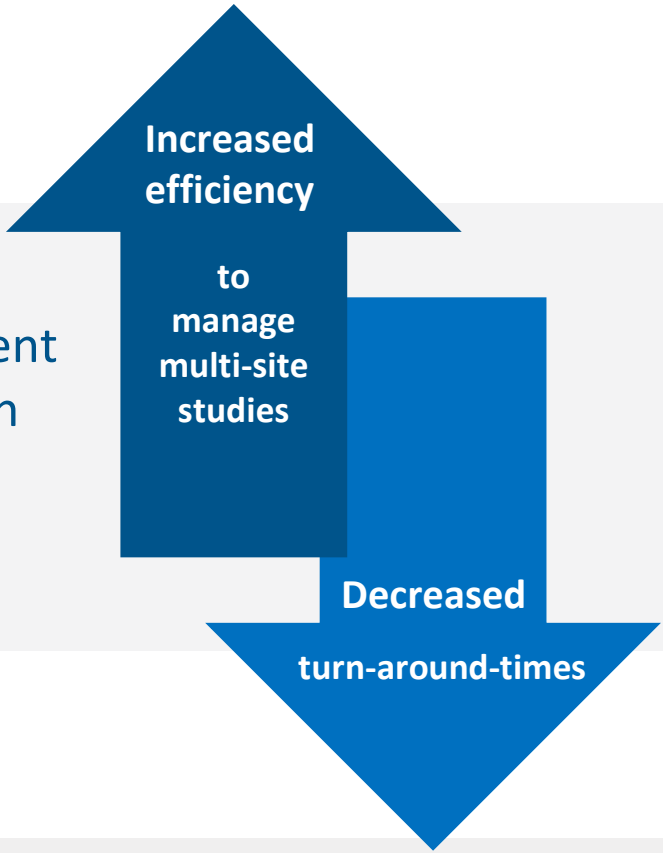
University of Wisconsin

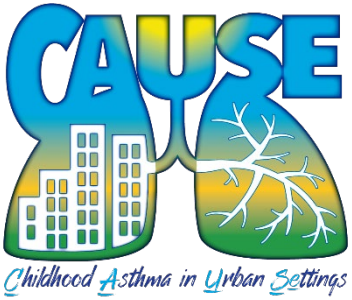
Academic IRB

What changed for CAUSE?

University of Wisconsin underwent an IRB transformation effort with Huron Consulting



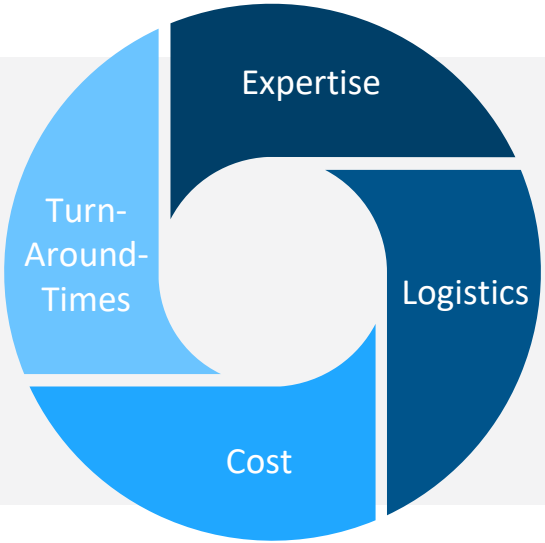




Pre-Award Decisions

Pre-Award

Selection of IRB



Pick two:

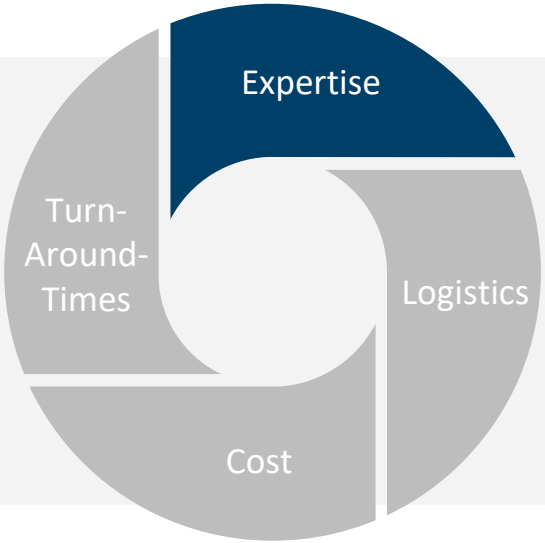
Good

Fast

Cheap

Pre-Award

Selection of IRB

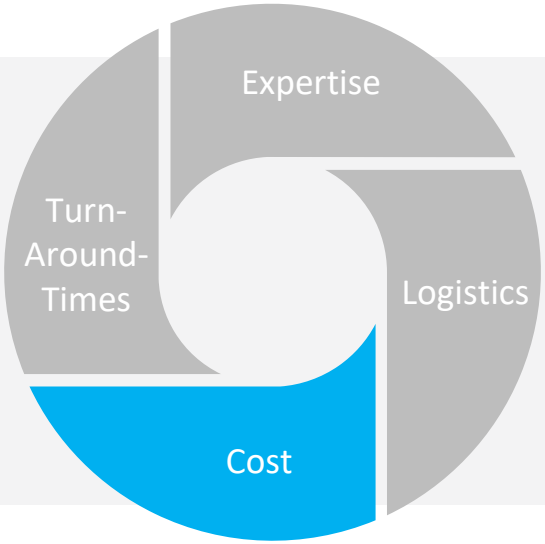


Procedures

Local Context

Pre-Award

Selection of IRB



Scenario	Awardee	sIRB
1	Institution A [1] • prime awardee • conducting the study	IRB at Institution A
2	Inst	

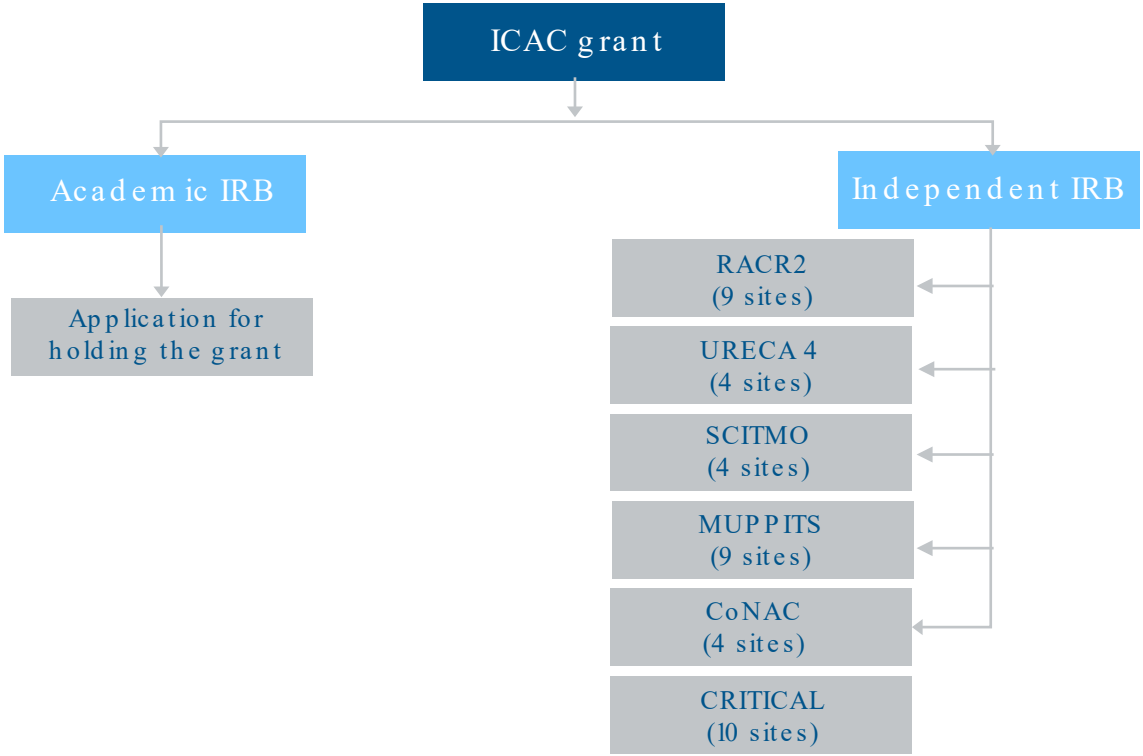
Participating Sites	How sIRB Costs Should Be Able to Be Charged
Institution A + 14 subawardees	• Primary activities are charged as Institution A's indirect costs because Institution A has a Federally approved F&A rate and is a participating site. • Secondary activities related to the other 14 participating sites may be charged as Institution A's direct costs.
14 subawardees	• Primary activities are charged as Institution A's indirect costs. Institution A is not a participating site,[2] but because OHRP policy generally considers prime awardees to be engaged even when all of the research is carried out by the subawardees, IRB review is required. • Secondary activities for the other 14 participating sites may be charged as Institution A's direct costs.

NOT-OD-16-109: Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research

SRA INTERNATIONAL

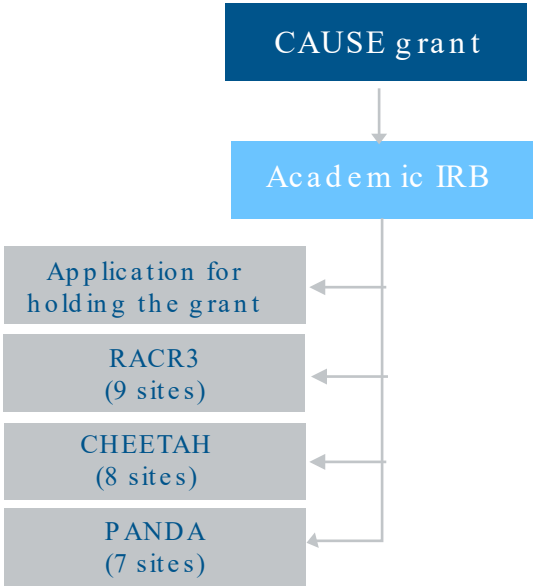
Pre-Award

Selection of IRB (cost)



Pre-Award

Selection of IRB (cost)



Pre-Award

Selection of **IRB** (cost)

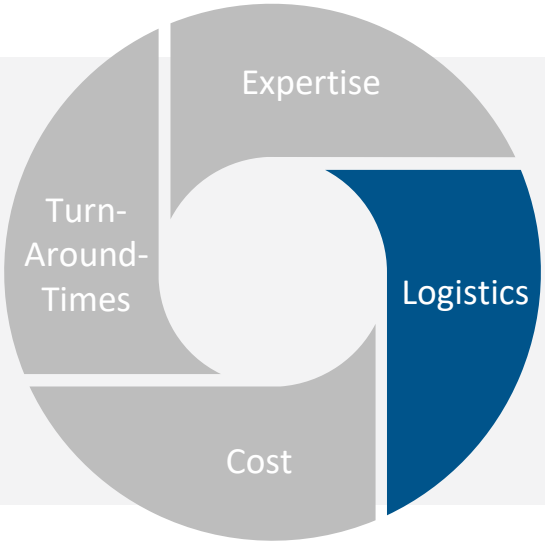
CAUSE Clinical Protocols	# of Submissions for 1 year
RACR3 (9 sites)	9 Site Reviews 16 Changes 1 Continuing Review
CHEETAH (9 sites)	9 Site Reviews 23 Changes 1 Continuing Review
PANDA (7 sites)	7 Site Reviews 32 Changes 1 Continuing Review

99 reviews x $1000 = $99,000

SRA INTERNATIONAL

Pre-Award

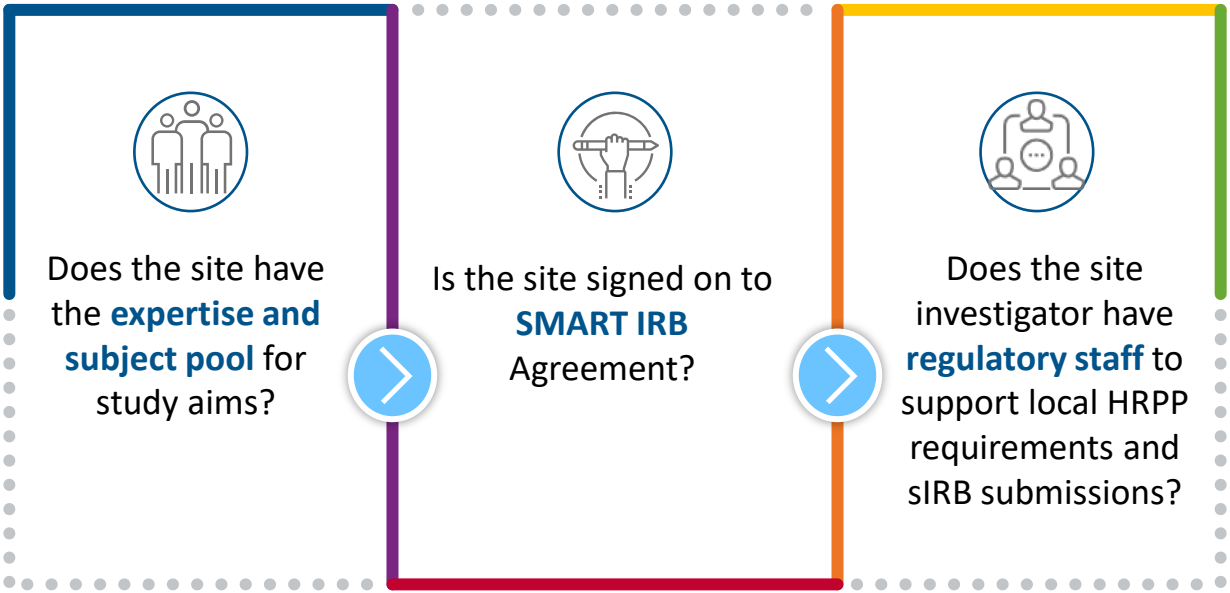
Selection of IRB



Logistic Consideration	Academic IRB	Independent IRB
System accessible to external personnel		✓
Direct communication of approvals to all sites		✓
Approval letters list all submitted documents for auditing/monitoring		✓

Pre-Award

Selection of **Sites**



SRA INTERNATIONAL

Pre-Award

Hiring an IRB Facilitator

01 REGULATORY SUPPORT

Manage IRB submissions for all sites

02 DOCUMENT DRAFTING

Consent templates, site specific protocol revisions and material

03 COMMUNICATION PLAN

Reporting IRB approvals and reportable events between sites and IRB

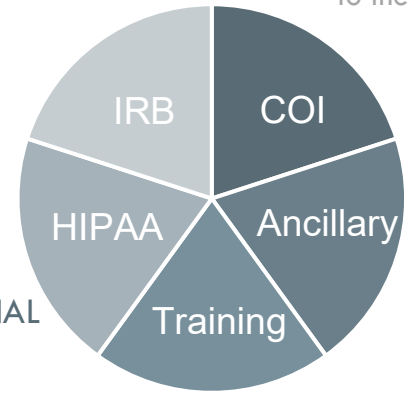
04 DOCUMENT STORAGE

Relying sites do not have access to academic IRB system

06 RELYING SITE QUESTIONS

Do I have to submit this to the IRB?

05 INSTITUTIONAL REVIEWS



Assist relying sites complete all ancillary reviews at their site

Pre-Award

Hiring an **IRB Facilitator** (cost)

Estimated Full Time Equivalent (FTE):
Depends upon the complexity of the study and the number of sites. It is estimated that most studies with 10 or more sites will require 1.0 FTE dedicated to this role. Smaller studies may be able to combine this role with another role such as general study coordination.

https://irb.wisc.edu/manual/reliance-manual/appendices/?tab=appendix-c-irb-liaison-job-description

Pre-Award

Hiring an **IRB Facilitator** (cost)

IRB Facilitator – Senior Level*					
Avg Annual Salary	Effort %	Fringe Rate – 36.5 %	Total Salary & Fringe	F & A rate – 55.5 %	Total Annual Cost
$90,000	30 % = $27,000	$9,855	$36,855	$20,454.53	$57,309.53

IRB Facilitator – Entry/Mid-Level*					
Avg Annual Salary	Effort %	Fringe Rate – 36.5 %	Total Salary & Fringe	F & A rate – 55.5 %	Total Annual Cost
$70,000	50 % = $35,000	$12, 775	$47,775	$26,515.13	$74, 290.13

*Example Costs

Pre-Award

Not Hiring an **IRB Facilitator** (cost)

> “…the value of a single day of delay is worth approximately $500,000 in unrealized or lost prescription drug sales and $40,000 in direct daily clinical trial costs.

KEN GETZ, APPLIED CLINICAL TRIALS VOLUME 33, ISSUE 6 (JUNE 2024)

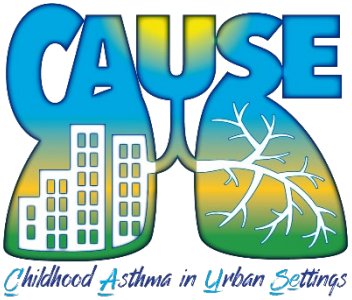
Pre-Award

Selection of Document Platform

Logistic Consideration	Academic IRB	Independent IRB
System accessible to external personnel		✓
Direct communication of approvals to all sites		✓
Approval letters list all submitted documents for auditing/monitoring		✓

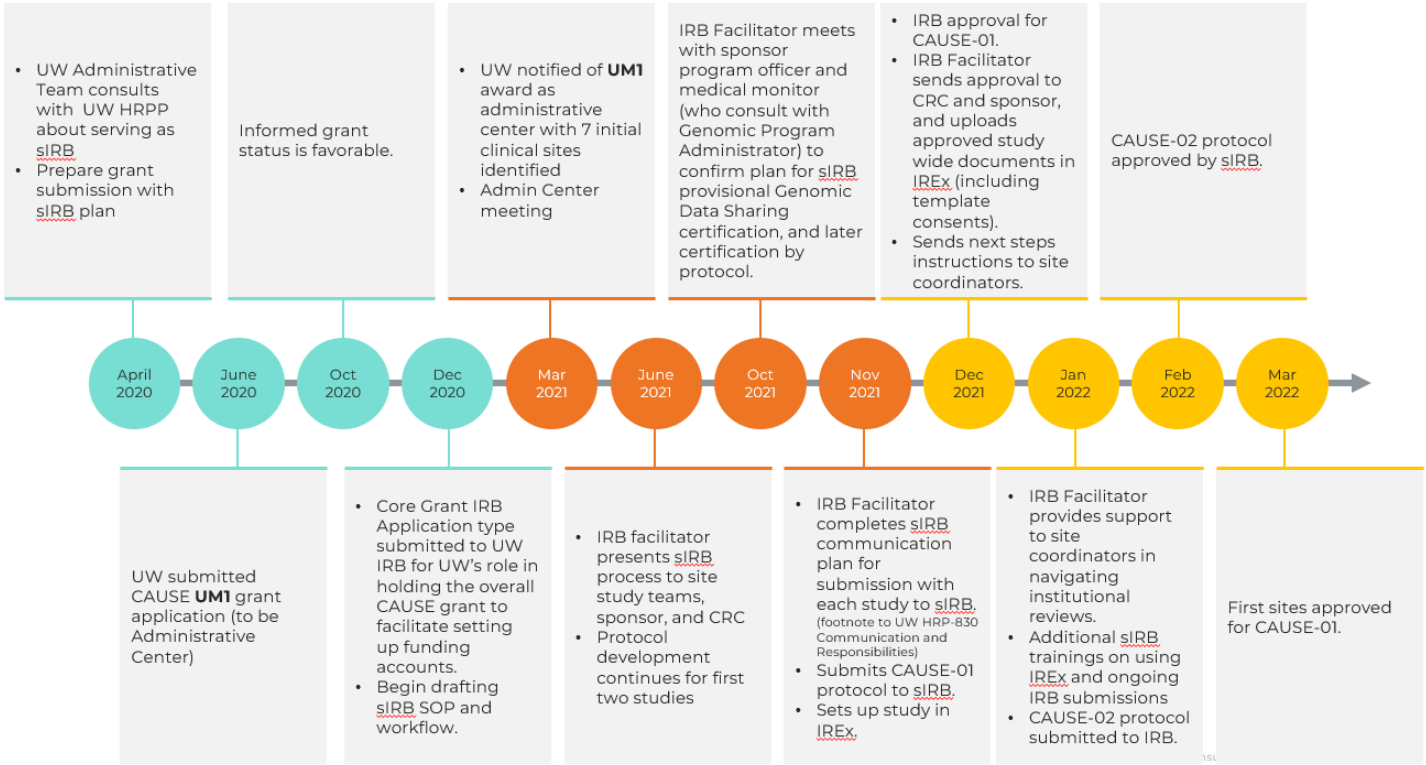
The CAUSE-LC proposes utilizing IRB Reliance Exchange (IREx) (https://www.irbexchange.org/p/) which is a web-based platform, supported by the Duke/Vanderbilt Trial Innovation Center and funded by NCATS, to facilitate sIRB documentation, communication, and the exchange of information for studies receiving sIRB support. The IREx system can be leveraged by the IRB facilitator to assist with document flow from initial approval through study closure between sIRB and relying sites.

IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW



Metrics

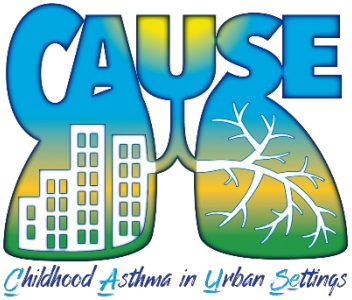
Pre-Grant Application to First Protocol/First Sites Approved



Metrics

	PROTOCOL	IRB Facilitator Submission to WIRB/UW (days)	WIRB/UW Review Protocol (days)	Site Reviews at WIRB/UW (days)	Site Institutional Reviews (days)		Site Start-up (days)*
					IRB	Ancillary	
ICAC, 2017	RACR2 (9 sites)	1	22	Ave. 7	Ave. 25.8 (range 3-76)	(0-120)	Ave. 184
	URECA 4 (4 sites)	1	24	Ave. 16	Ave. 24 (range 1-51)	(0)	Ave. 93
	SCITMO (4 sites)	1	15	Ave. 6	Ave. 15 (range 7-32)	(0-93)	Ave. 213
	MUPPITS (9 sites)	1	9	Ave. 7	Ave. 11 (range 3-37)	(0-35)	Ave. 145
	CoNAC (4 sites)	1	11	Ave. 12	Ave. 14 (range 3-24)	(0-12)	Ave. 114
CAUSE, 2021	RACR3 (9 sites)	1	18	Ave. 3	Ave. 24 (range 6-46)	DAIT RMC (15-32)	66
	CHEETAH (8 sites)	1	35	Ave. 9	Ave. 32 (range 6-45)	DAIT RMC (30-91)	155
	PANDA (7 sites)	1	14	Ave. 3	Ave. 37 (range 15-57)	DAIT RMC (18-85)	112

*as measured from the date of protocol version 1 to date site received activation letter from Statistical and Clinical Coordinating Center



Anecdotal Challenges

Questions from Site Coordinators

Identify a single point of contact for IRB related questions. Draft an FAQ.

- We need the following documents for our reliance application that aren't in IREx:
  - o 1572 (FDA)
  - o the risk level the IRB assigned (e.g., regulatory category for a study involving children)
  - o scientific portion of the grant application
  - o IAA (reliance agreement)

- The site HRPP wants to change the assent form and process from what the sIRB approved (e.g., our site has a policy that we must obtain written assent but the sIRB approved verbal assent)
- How do we draft a separate HIPAA Authorization (my site doesn't normally do that)?
- Not all subject material is stored in IREx. Where do I get the subject material that the sIRB said they don't have to review but are part of the study documents (e.g., appointment reminder card, non-study procedure related Case Report Forms)?

Transparency of Review Status

The multitude of moving pieces in a sIRB model does not lend to transparency in the status of a study's approval process.

A status chart for each protocol under the grant helps provide an update to stakeholders.

Site	Status of Reliance & Local Context Surveys (IREx) Site HRPP	Site Documents Provided (to IRB facilitator) Site Study Team	Site Documents Outstanding (e.g., Delegation Log) Site Study Team	sIRB Site Submitted Date/Status IRB Facilitator

Logistics and Documentation

- Consider a **file share mechanism** like Box for sites to provide tracked change material or large amounts of site-specific recruitment material to an IRB facilitator submitting to single IRB on behalf of sites.
- Sponsor monitors or auditors may require proof of submission of each document to the IRB and the IRB approval letter may not list all documents. IRB facilitator in this case must "PDF" the IRB application for each site to prove what was submitted or create a separate **document that lists submitted material** and outcome.
- Academic IRB may **require use of local protocol template** instead of NIH template.
- Academic IRB may require **parent/child model of review** where protocol and template documents must be submitted and approved prior to relying site submissions.

Anecdotal Challenges

Filling the IRB Facilitator Role

No standard training available for an IRB Facilitator

Difficult to fill a part-time role able to bridge regulatory, science, and knowledge of sites

Summary Budget Considerations for sIRB Selection

- IRB Facilitator Costs
- Burn Rate of Dormant Network (Turn-Around Times)
- Average Annual Cost of IRB Fees

Questions?

IRB Facilitator
Document Storage
Additional Regulatory Time

Expertise
Cost
Logistics
Turn-around-Times

sIRB and Sites Signed on to SMART IRB Agreement
HRPP has Posted Guidance

Objectives

1. Identify indirect costs associated with sIRB logistics for large grants involving multi-site human subjects research.

2. Describe three considerations for sIRB selection and analyze participating sites sIRB readiness.

Contact Information

Kellie Hernandez
Distinguished Research Program Manager and Director of CAUSE grant
khernand@medicine.wisc.edu

Brandy Stoffel, JD, CIP
Education and Research Consulting Senior Associate
bstoffel@hcg.com

University of Wisconsin
SCHOOL OF MEDICINE AND PUBLIC HEALTH

HURON