

IRBSHARE: PAST, PRESENT AND FUTURE

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IRBSHARE: DEVELOPMENT HISTORY

- Familiar History of IRB Reviews for Multi-site Studies
 - + Cause significant duplication of effort
 - + Create increased time and resources
 - + Result in inconsistent findings and requested changes
Prevention or delay of study start up and increased costs
- Dr. Jerry Menikoff, Director, Office for Human Subjects Projects (2009): "Existing regulations are not designed for multi-site review"

R13: "NOVEL IRB MODEL(S) FOR EFFICIENT MULTI-SITE REVIEW

- Meeting 1 (June 2011): Representatives from 37 CTSA sites, OHRP, AAHRPP, VA, Independent IRB, & Industry met in to discuss workflow around IRBshare
- Results of Meeting 1
 - IRBshare Model
 - IRBshare Master Agreement (IMA)
 - IRBshare System (www.IRBshare.org)

GOALS OF NEW IRB REVIEW MODEL(S) FOR MULTI-SITE STUDIES

- At least maintain if not improve human subjects protection
 - Standardize best practices through evaluation & monitoring
 - Improve IRB efficiency for multi-site studies (e.g., faster IRB reviews / approvals; reduced manpower / \$ for reviews)
 - Enhance IRB communication & cooperation (e.g., more consistent determinations and the ability to “consult”)
 - Minimize contracts/paperwork
 - Maintain local IRB flexibility and autonomy
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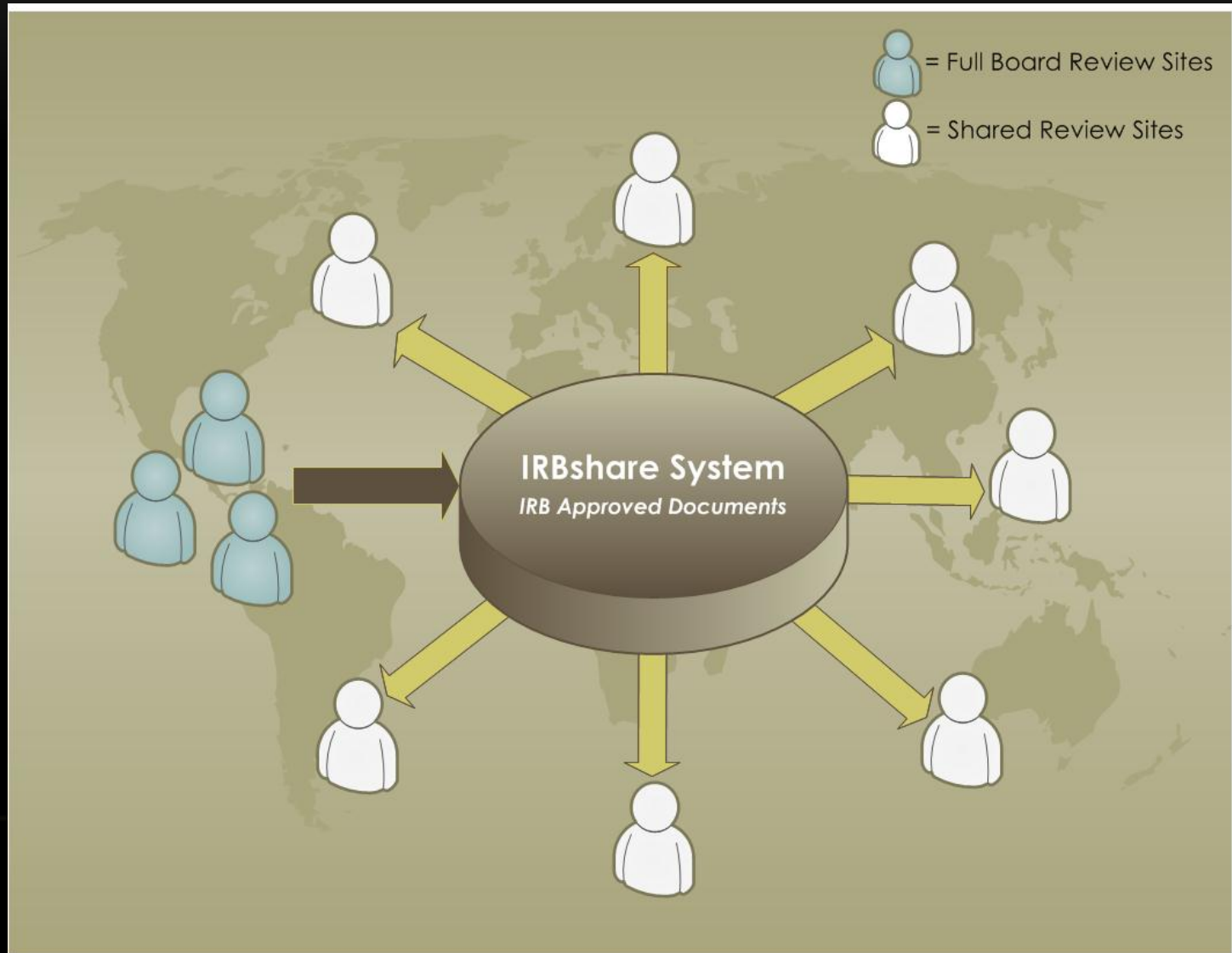
IRBSHARE

- Novel IRB review model for multi-site studies
 - Facilitates the **sharing** of full board review documents
 - Enables a **temporary reliance** between IRBs for the initial study review (for now)
 - Supported by secure **web-based document sharing system**
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IRBSHARE IS NOT A CENTRALIZED REVIEW MODEL

COMPONENT	IRBshare	Central IRB
Type of Agreement	One-time, multi-party	Study-specific
Length of Reliance	Temporary	Life of the study
Review Options	<ul style="list-style-type: none"> • IRBshare shared review • Local full board 	Central IRB review
Reviews Available	≥ 1 FBRs from different IRBs	≥ 1 central IRB's reviews
Local Context Responsibility	Local IRB	<ul style="list-style-type: none"> • Local IRB • Central IRB
Reporting Responsibilities	Unchanged	Report locally and/or to Central IRB
Forms Submitted by PI	All local forms	All/some templates (e.g., consent form)

IRBSHARE: MULTI-SITE STUDY REVIEW MODEL



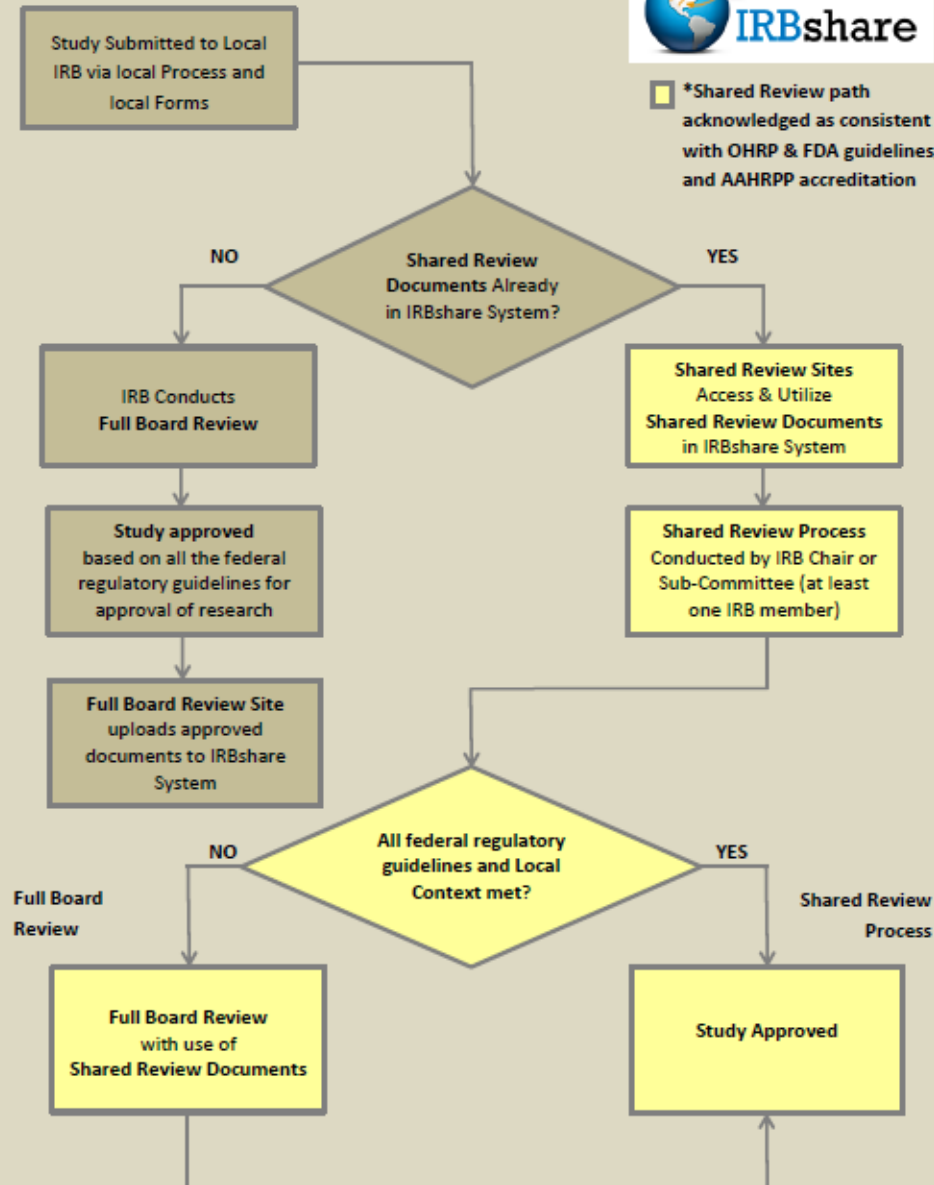
LOCAL IRB REVIEW USING IRBSHARE

- Local forms and submission processes do not change
 - Ability to access any Shared Review Documents from multiple IRBs for a study (*if multiple are uploaded*)
 - Ability to consult the Shared Review documents to facilitate their Full Board Review
 - Continuing review date is based on the Full Board Review site's approval date
 - Indicate IRB of Record for initial study review in IRBshare; email notifications are sent to the Shared Review Site and the Full Board Review site being relied upon
 - No document to upload when utilize the Shared Review (i.e., rely upon another site)
 - Option to review locally, via site's full board, is always available
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IRBshare Concept



*Shared Review path
acknowledged as consistent
with OHRP & FDA guidelines,
and AAHRPP accreditation



REGULATORY ACKNOWLEDGEMENTS RECEIVED

- OHRP and FDA have acknowledged IRBshare as a permissible model for joint review (45 CFR 46.114 & 21 CFR 56.114)
- AAHRPP has acknowledged IRBshare is consistent with accreditation standards

IRBSHARE MASTER AGREEMENT

DECISIONS

- All participating institutions sign the same agreement
- Two-part agreement: Master agreement and Operator Appendix
- Open to any organization with an active Federalwide Assurance with OHRP
- Cannot restrict Participating Institution(s) from relying upon a shared review
- Reliance is only for initial study review (*at this time*)
- Local site is responsible for local context review
- Local site becomes IRB of Record after initial study review
- Include indemnification language (*but not the term*)

FEEDBACK

- + Reduce paperwork by creating one-time agreement
- + Allowing multiple Shared Review Sites enables sites who are recruited late more time before their continuing review
- + Shared review model increases opportunity to learn from other institutions' expertise
- Not all institutions are comfortable with terms
 - Inability to limit who relies on a shared review
 - Concern about local context responsibilities

POTENTIAL BENEFITS OF IRBSHARE (FOR STUDY STAFF AND THE IRB)

- The short term:
 - More efficient/shorter review times for initial study review
 - Reduction in study start up time
 - More consistent determinations and requested changes
 - More attractive multi-site study site because of efforts to streamline IRB review
 - Collaboration with other IRBs
 - Learn how other IRBs interpret the regulations
 - Maintain local control of the study
- Future benefits:
 - Innovation within the IRB (e.g., databases, streamlined applications, template consent forms)
 - Collaborative network of IRBs to better facilitate changes to the regulations and research environment
 - Potential to foster similar collaborations with contracts

IF IT'S NOT BROKEN, DON'T FIX IT!

- Local IRB submission processes and forms will not change
 - Study coordinating centers will continue to facilitate communication between PIs and study teams regarding IRB submission best practices and language
 - Adverse event reporting is still reported locally: no new system of reporting or individuals to notify
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IRBSHARE: PARTICIPATING INSTITUTIONS

25 Participating Institutions

- 22 CTSA institutions
- 17 AAHRPP accredited institutions

Institution	CTSA	AAHRPP
Baystate Health (MA)		YES
Boston University Medical Center	YES	
Duke University	YES	YES
Maine Medical Center		YES
Marshall University	YES	YES
Medical Center of South Carolina	YES	YES
Meharry Medical College	YES	
Mount Sinai Medical School	YES	YES
North Shore LIH Health Systems		
Stanford University	YES	YES
The Scripps Research Institute	YES	
Tufts University	YES	
University of Alabama Birmingham	YES	YES
University of Illinois at Chicago	YES	YES
University of Iowa	YES	YES
University of Kentucky	YES	YES
University of Miami	YES	
University of Minnesota	YES	YES
University of North Carolina at Chapel Hill	YES	YES
University of Southern California	YES	YES
University of Texas HSC San Antonio	YES	YES
University of Texas Southwestern Medical Center	YES	
University of Washington	YES	
Vanderbilt University	YES	YES
Virginia Commonwealth University	YES	YES

IRBSHARE PILOT PHASE

- Any institution with an active Federalwide assurance with OHRP
- ~~NIH funded multi-site study undergoing new/initial study review~~

Study	ISCHEMIA Trial Lead site: NYU	Neonatal Abstinence Syndrome Lead site: Tufts	MENDS II Lead site: Vanderbilt	Anti-hypertension Lead site: Iowa
# Sites	80 using local IRB	5	5	2
# Study sites in IRBshare	12	4	3	2
# Full Board Reviews Available in IRBshare	<ul style="list-style-type: none"> • University of Iowa • University of Kentucky • Vanderbilt University 	<ul style="list-style-type: none"> • <i>Tufts University*</i> 	<ul style="list-style-type: none"> • Vanderbilt University 	
# Shared Reviews Completed OR Planned	<ul style="list-style-type: none"> • Duke University (relied upon Vanderbilt) 	<ul style="list-style-type: none"> • <i>Vanderbilt University*</i> • <i>Maine Medical Center*</i> 	<ul style="list-style-type: none"> • <i>Baystate Health*</i> 	

PILOT PHASE: USER EXPERIENCE WITH SHARED REVIEW

Duke Completed First Shared Review

- No problems with the shared review
- IRB staff conducted administrative review prior to the Senior IRB Chair's Shared Review
- Chair looked at all reviews available, similar to the external review procedures
- IRB documented use of IRBshare in current IRB database (Click Commerce)

PILOT PHASE: SHARING BEST PRACTICES

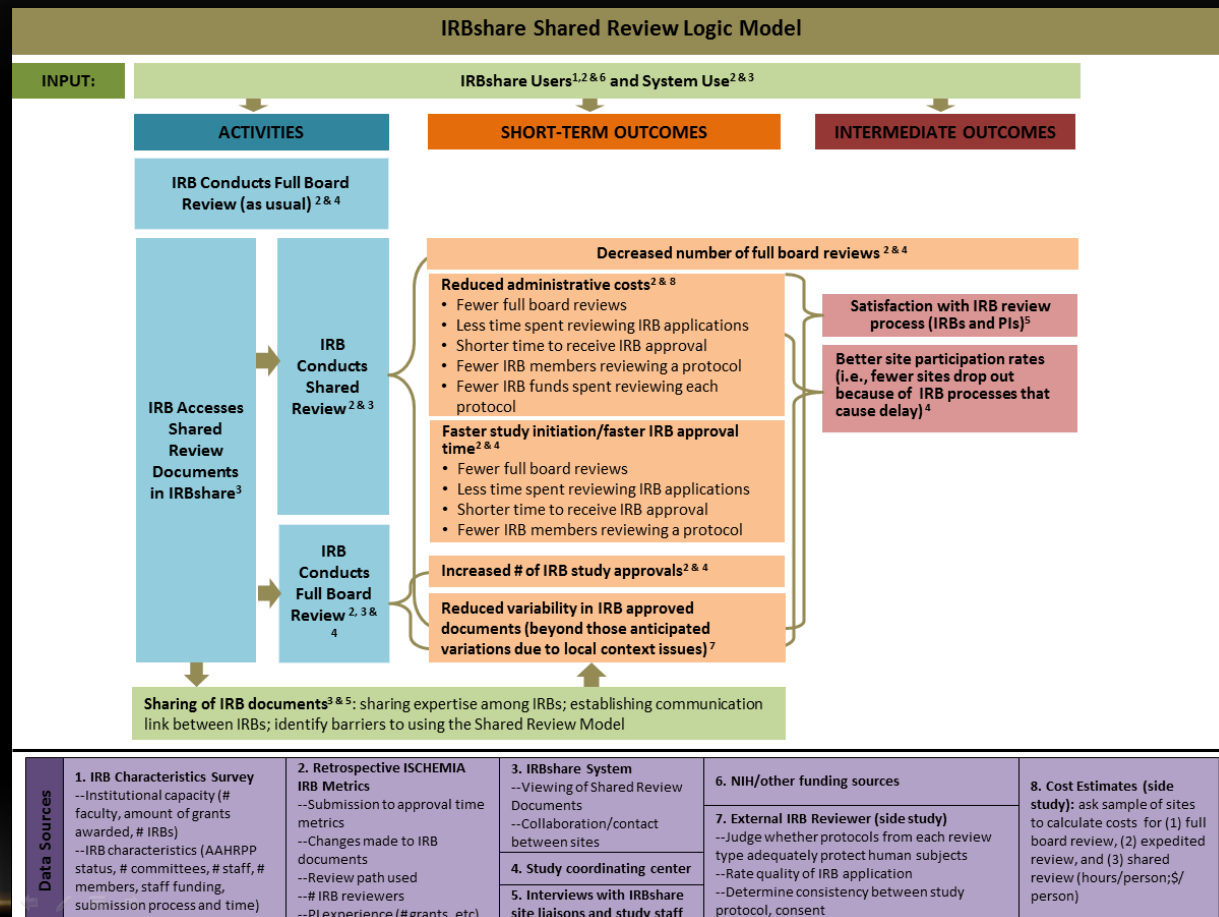
- When applying for AAHRPP accreditation, an institution modeled their meeting minutes template on the minutes uploaded as part of a shared review
- Not all meeting minutes are taken without names
- IRBs without electronic systems require substantial time to upload shared review documents
- Reduction of paperwork for PIs:
 - IRBshare institution created 'abbreviated' IRB application for studies submitted locally after full board approval uploaded to IRBshare
 - PIs will only submit abbreviated application (i.e., local context issues), consent form, and cover letter (template provide) instead of full IRB submission

PILOT PHASE: EARLY LESSONS LEARNED

- Educate PIs prior to grant submission
- Get IRBs on board prior to study submission to the IRB
- Spreading the news to PIs, NIH program officers, research networks
- Continue to develop the model and system to include continuing reviews and amendments

IRBSHARE EVALUATION

- Reduced administrative costs
- Faster review cycle times
- Faster study initiation
- Increased # of IRB study approvals
- Fewer differences in number and type of changes requested to study documents
- Increased partnership satisfaction levels
- Learning from collaborations
- Explore ways to expand IRBshare



DATA COLLECTION FEASIBILITY STUDY: EVALUATION PHASE 1

- Assess the feasibility of collecting data from IRBs
- Determine the best method for collecting data from IRBs
 - 1-part vs. 2-part survey
 - Phone vs. email outreach
- Conduct qualitative interviews on user satisfaction, system needs, and barriers and facilitators to using the Shared Review Process

IRBSHARE: FUTURE DIRECTIONS

- Revise shared review model and IRBshare Master Agreement (IMA) to include other review types (amendments and continuing reviews)
- Focus on educating PIs/study teams to increase adoption early in study timeline
- Display system metrics on public-facing website (e.g., # participating institutions, # studies, # shared reviews)
- Begin developing more features in IRBshare System
 - Streamlining communication between IRBs within IRBshare
 - Reporting capabilities: report showing where site is IRB of Record and where ceded initial study review
 - Documented continuing reviews and amendments

IRBSHARE SYSTEM DEMO

- IRBshare.org
- User dashboard
- Multiple user types and role-based permissions
- Project searching
- Document IRB review path (Full/Shared)
- Document dates of submission, review, approval
- Upload Shared Review Documents
- Facilitate connections between IRBshare liaisons