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Relying on someone else's IRB

Why, When, and How for Hospitals and Academic Medical Centers



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Objectives

- **Why IRB reliance is valuable:** the landscape of IRB reliance including the NIH single IRB policy, why it matters, and what it means for hospitals and academic medical centers
- **When you should rely:** defining your institutional risk tolerance and when you should accept an external IRB's review, drafting your institutional policy for reliance, and identifying the information you need to rely
- **How to rely:** understanding the responsibilities of your institution, investigators, and IRB and implementing processes to fulfill them; drafting reliance agreements based on your risk tolerance; collecting and providing local context information



WHY rely



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What is reliance?



Reliance: the process in which multiple institutions are engaged in the research and one institution agrees to rely on the IRB of another



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Why should you rely?

- Efficiency
- But mostly...because you have to
 - NIH Single IRB Policy
 - Common Rule – 45 CFR 46 (2020)
 - Sponsor mandates





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NIH Single IRB Policy (2018)

“...all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.”

Common Rule (45 CFR 46.114, eff. 2020)

“Any institution in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.”



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What reliance means for you

- TRUST
- Not more or less work, just different work
- Redefined responsibilities (institutional vs. IRB)



WHEN to rely

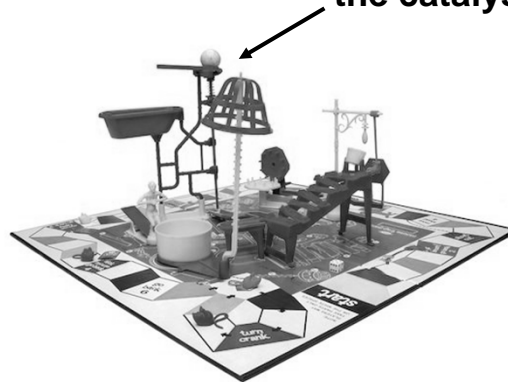


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Understand your role

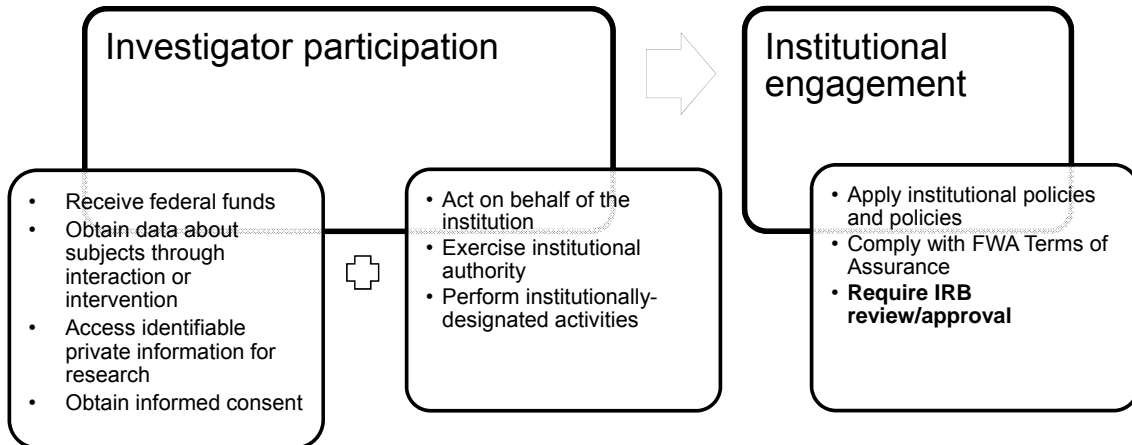
- Are you **engaged**?
- If so, you are subject to regulatory requirements for human subjects protection – i.e. IRB review

Engagement is the catalyst

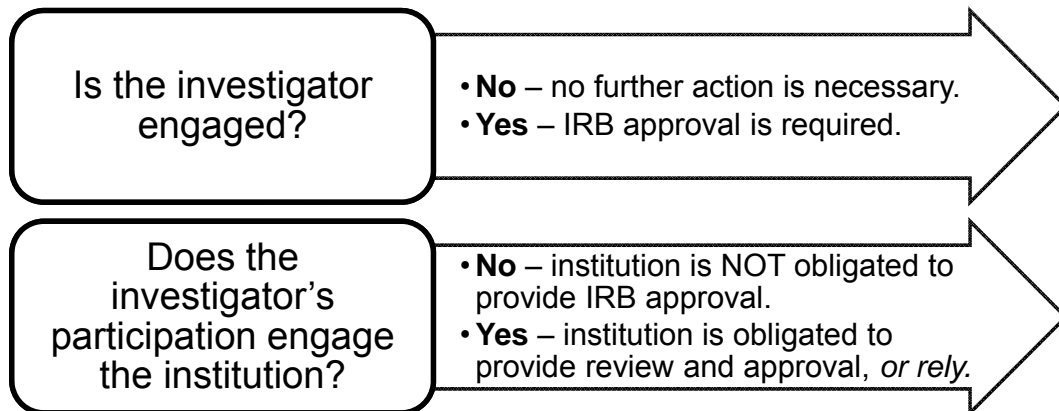




Understanding engagement



Applying engagement





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Engaging the institution

Yes:

- Acting within the scope of their employment (agency) or on behalf of their institution
- *Example:* nurses conducting research as part of their employment

No:

- Employed by an institution but not acting within the scope of employment
- *Examples:* employees volunteering their services for research, nurses conducting research for their graduate degree



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When NOT to rely

- Other laws require local IRB review
- Your institutional risk tolerance discourages you
- Your institutional policy prohibits reliance



When NOT to rely



Is there a better option?

Consider additional safeguards

- Training
- Local requirements
- Auditing



Prepare for reliance

- Understand your risk tolerance
- Be ready to sell it
- Ask the hard questions
 - What does local IRB review gain us?
 - Why does it make us feel better?
 - What can our IRB do better than others?



HOW to rely



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Know your responsibilities

- Single IRB review \neq single institutional review
- Under reliance, only the IRB responsibilities are delegated
- Each relying site retains responsibility for institutional responsibilities



Image adapted from Singleton, Megan Kasimatis. "So what is local context review and how do I do it?" Public Responsibility in Medicine & Research (PRIM&R) 2017 Advancing Ethical Research Conference. San Antonio, TX. November 5-8, 2017.



Know your responsibilities

- Education/training
- Conflicts of interest
- Institutional reviews
- Local context
- HIPAA compliance
- Monitoring
- Notification
- Communication



Create a reliance agreement

- Defines the responsibilities and expectations of **both institutions** in a reliance situation
- Required by
 - Terms of the FWA
 - Common Rule
 - NIH Single IRB Policy

- Scope & invocation
- **Responsibilities:** single IRB and the relying institution
- Communication & notification
- Auditing & monitoring
- Confidentiality
- Insurance & indemnification



Models of reliance agreements

- Master agreements
 - SMART IRB
 - Independent IRBs
 - Consortia or disease-specific agreements
 - Regional
- Study-specific agreements



Provide local context

- The information a reviewing IRB needs in order to review your research
 - State & local laws
 - Institutional policies
 - Consent language
- Be specific and consistent
- Update periodically or when things change





Create a process

- Tracking your research
- Customize your process to meet your needs
- Focus on fulfilling your institutional responsibilities
- Check all the boxes (e.g. reliance agreement, local context, etc.)



Educate investigators

- Your reliance process
- What reliance means
 - Debunk the myths
- Their responsibilities
 - Obtaining IRB approval
 - Knowing the reviewing IRB's policies and procedures



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Other considerations

- Resources/staffing
- Policies
- Post-approval monitoring



Takeaways

- You can't avoid reliance. **Be ready.**
- There are no perfect processes. **Be creative.**
- This is an evolving area. **Be flexible.**
- It's not just about you anymore. **Be collaborative.**

