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2024 AAHRPP Webinar Series

HRPPs and Single IRB: A Landscape Analysis

Presenters:

Joshua Fedewa, MS, CIP, Director, IRBMED, University of Michigan

Megan Kasimatis Singleton, JD, MBE, CIP, Associate Dean, Human Research Protections and Director of the Human Research Protections Program, Johns Hopkins University School of Medicine

Moderator: **Nichelle Cobb**, PhD, CIP, Senior Advisor for Strategic Initiatives, AAHRPP

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Format for 2024

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- Livestreamed Content
- Live Q&A
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Webinar Sessions

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- One Attendee Hub
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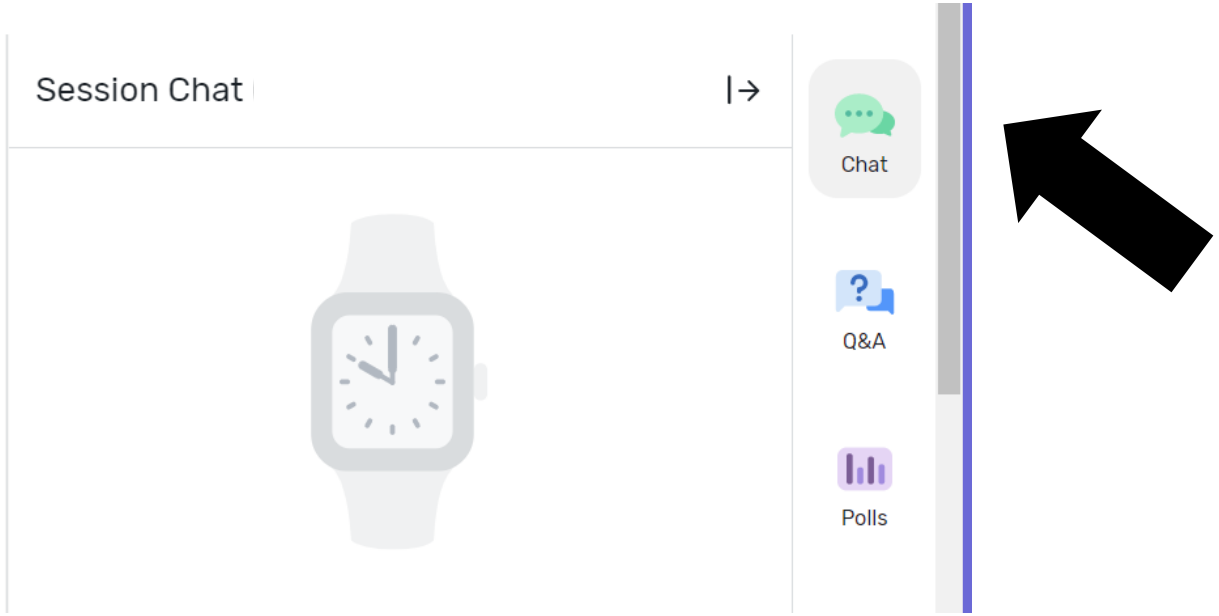

Questions

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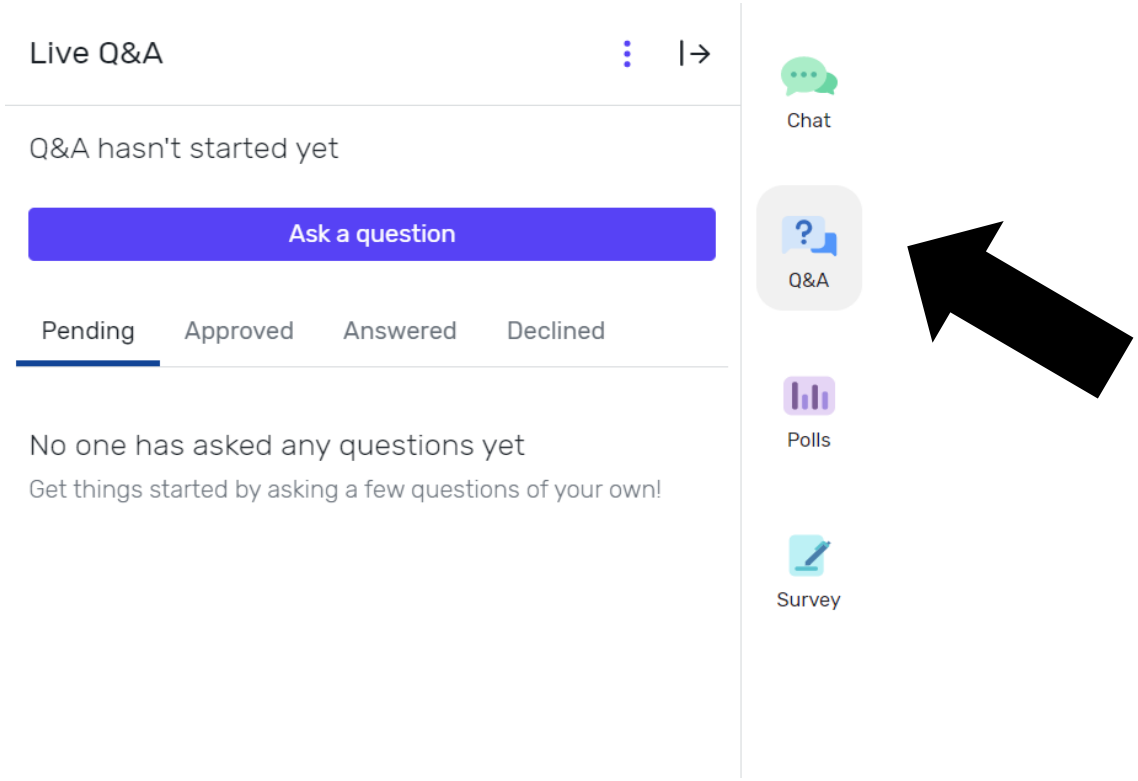

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Upcoming Webinars

Ask... AAHRPP®

Save these dates for the remaining 2024 "Ask AAHRPP" webinars:

- April 9, 2024
- June 11, 2024
- August 13, 2024
- October 8, 2024
- December 10, 2024

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- July 9, 2024
- November 12, 2024

Visit Webinars (aahrpp.org) for more information and registration links

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Presenter Introductions

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Joshua Fedewa

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Megan Kasimatis Singleton

Johns Hopkins University
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What is Standard I-9?

This Standard outlines AAHRPP's requirements for when organizations share oversight of research with another organization to ensure the rights and welfare of research participants are protected.

- Although the Standard primarily focuses on IRB (or ethics committee, EC) review, shared oversight can include other services (e.g., a contracting office or conflict of interest committee) of another organization to supplement its resources
- If an organization relies on the services of another organization, policies and procedures must describe the steps followed to ensure that the reviewing IRB or EC, or other service, protects the rights and welfare of human research participants

Content of Standard I-9

This Standard describes

- Policy and procedure requirements
  - For accredited organizations that provide IRB/EC review services to other entities
  - For accredited organizations that rely on another organization's IRB or EC
- The requirement to have a written agreement or policies and procedures that describe the distribution of responsibilities between the organization conducting the IRB or EC review and the relying organization

Relying on non-accredited IRBs/ECs

If an accredited organization relies upon a non-accredited IRB or EC, it should ensure the IRB or EC provides appropriate human participant protections, given the risks of the research, based on the risks the research poses or if required to rely on an organization with significant regulatory issues or other problems

Examples for Minimal Risk Research

- The organization may:
  - Obtain an assurance from the non-accredited IRB or EC that it will conduct its review consistent with the applicable ethical standards and regulations, and that it will report any regulatory violations or investigations of the reviewing IRB or EC by regulatory agencies, such as OHRP, the FDA, or regulatory agencies in other countries.
  - Request the reviewing IRB or EC to attest that it has completed its own internal quality review process, such as use of AAHRPP's Evaluation Instrument for Accreditation to conduct a self-assessment, completion of the US FDA's self-evaluation checklist for IRBs or ECs, or another process satisfactory to the relying organization.

Examples for Greater than Minimal Risk Research

- The organization may:
  - Review relevant portions of the minutes of the IRB or EC meeting where the particular study is reviewed.
  - Review IRB or EC records of the particular study being reviewed.
  - Evaluate relevant policies and procedures of the reviewing IRB or EC.
  - Observe a portion of an IRB or EC meeting where the particular study is reviewed.
  - Have someone from the relying organization serve as a consultant to the non-accredited IRB or EC for review of a particular study.
  - Conduct not-for-cause monitoring of the IRB or EC.

Organizations can meet Standard I-9 for shared IRB oversight if they use the SMART IRB Agreement

More information about SMART IRB is at https://smartirb.org/

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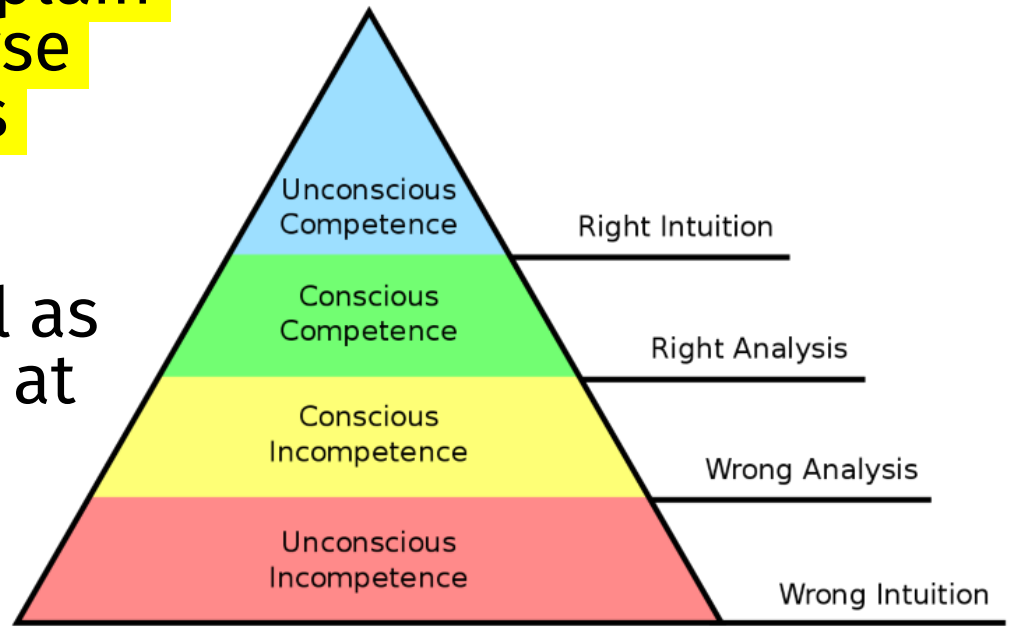
Where are we now? What's happening in the world of sIRB review?

Where are we now: Conscious Competence

- "Conscious competence is the third of the Four Stages of Competence. We've finally learned something new. Now we actually understand what we're doing and can explain how and why something works. We analyse the situation we're in, and our analysis is correct. How did we get here? Through practice and experience. Consciously competent learners tend to function well as long as they can concentrate on the task at hand." [1]



- [1] https://themindcollection.com/four-stages-of-competence/

Where are we now: Stages of Development

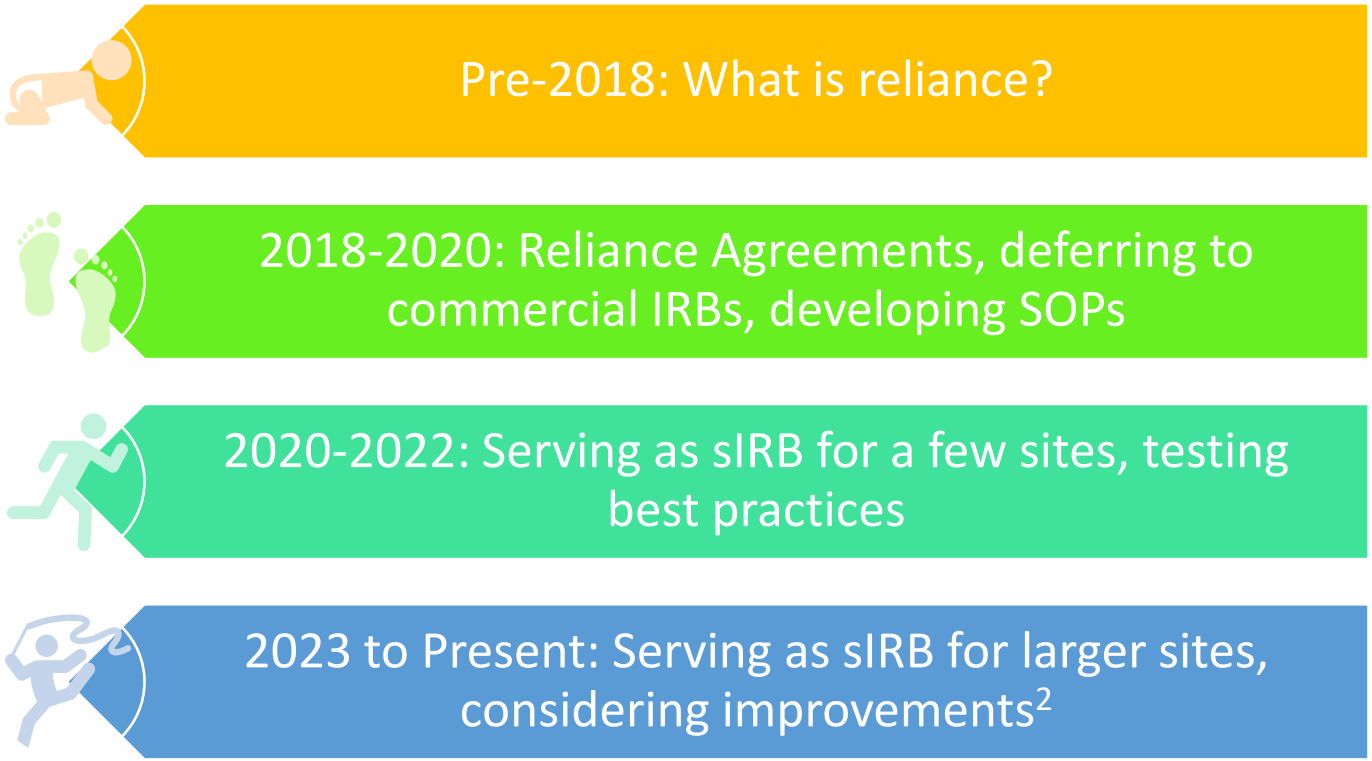
0-1: Crawling, sit up, standing

1-2: Walking, walking backward

2-3: Running, jumping, kicking

3-5: Somersaults, riding a bike

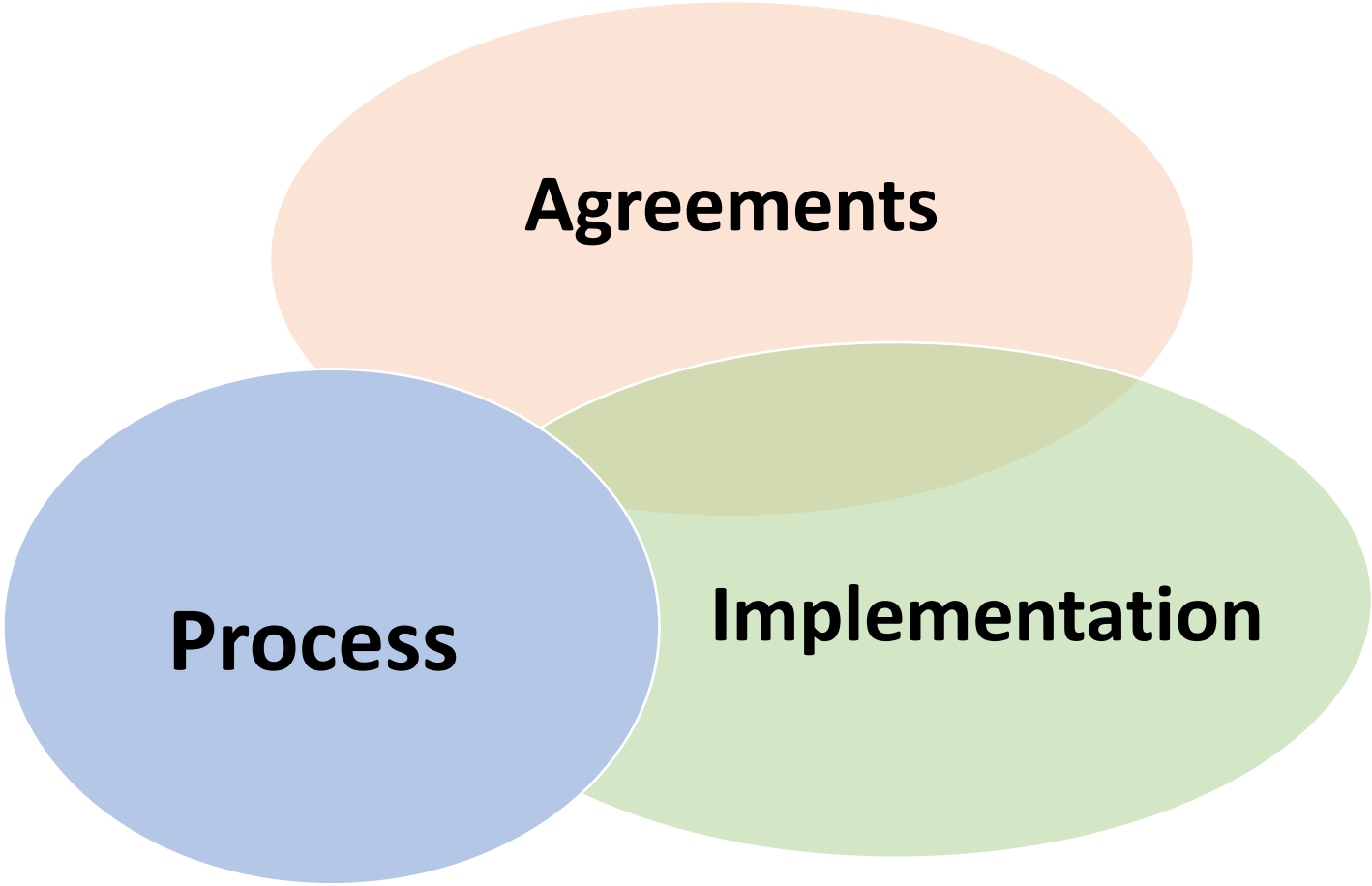
Where are we now: Stages of Development (cont.)



- [2] https://primr.org/PRIM_R_PROD/media/PRIMR/Documents/Public%20Policy/2022/PRIMR-Comments-on-FDA-NPRM-on-sIRB.pdf

Where are we now: Top Struggles identified through the Accreditation Process

Top challenges were derived from real life examples. They were compiled from the observations of AAHRPP site visitors and fall into three different types of challenges.



Agreements

Lack of specificity about roles and responsibilities of Reviewing IRB and Relying Institution	Failure to address reporting responsibilities and process	Failure to confirm who is responsible for ancillary reviews (e.g. conflict of interest)

Process

Failure to define a process for collecting local context information (as the sIRB) or performing a local context review (as the relying organization)	No process existed for sharing outcomes of ancillary reviews (e.g. COI management plans)	No process existed to coordinate reviews of reportable events

Implementation

Failure of the sIRB to communicate findings to relying sites	Failure of reviewing IRBs and relying organizations to coordinate reporting of reportable events	Failure of the sIRB to make policies and procedures available to relying sites

What can we learn from these challenges?

- Agreements serve as the play book and define whose job is it to perform each task
- Agreements are NOT Standard Operating Procedures (SOPs) – separately each organization has to make a plan for how it will fulfill responsibilities as outlined in any agreement
- Once processes are defined it is important to ensure they are implemented in accordance with any SOPs/agreements - Adopt mechanisms to monitor adherence to policy/procedure

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Top Challenge Area- Operationalizing sIRB Review

Challenges Identified

- New responsibilities for study teams
- Differentiation in local context review
- Lack of harmonization
- Need for greater flexibility and exceptions
- Variation in how to handle non-compliance

References

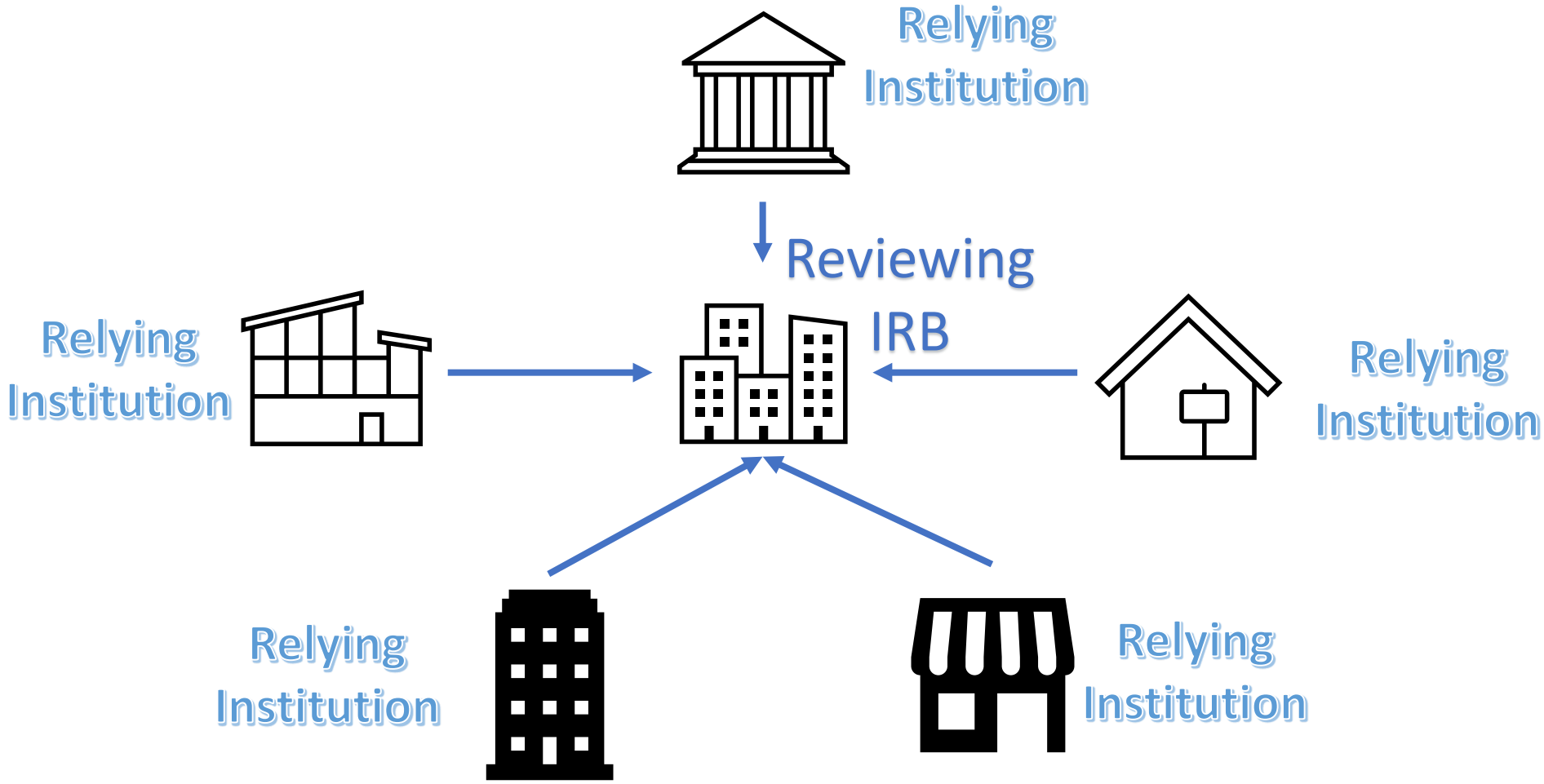
- Johnson, A. , Singleton, M., Ozier, J., Serdoz, E., Beadles, J., Maddox-Regis, J.... Bernard, G. (2022). Key Lessons and Strategies for Implementing Single IRB Review in the Trial Innovation Network. Journal of Clinical and Translational Science, 1-16. Doi: 10.1017/cts.2022.391.

- Green JM, Goodman P, Kirby A, Cobb N, Bierer BE. Implementation of single IRB review for multisite human subjects research: Persistent challenges and possible solutions. J Clin Transl Sci. 2023 Apr 4;7(1):e99. doi: 10.1017/cts.2023.517. PMID: 37250991; PMCID: PMC10225260.

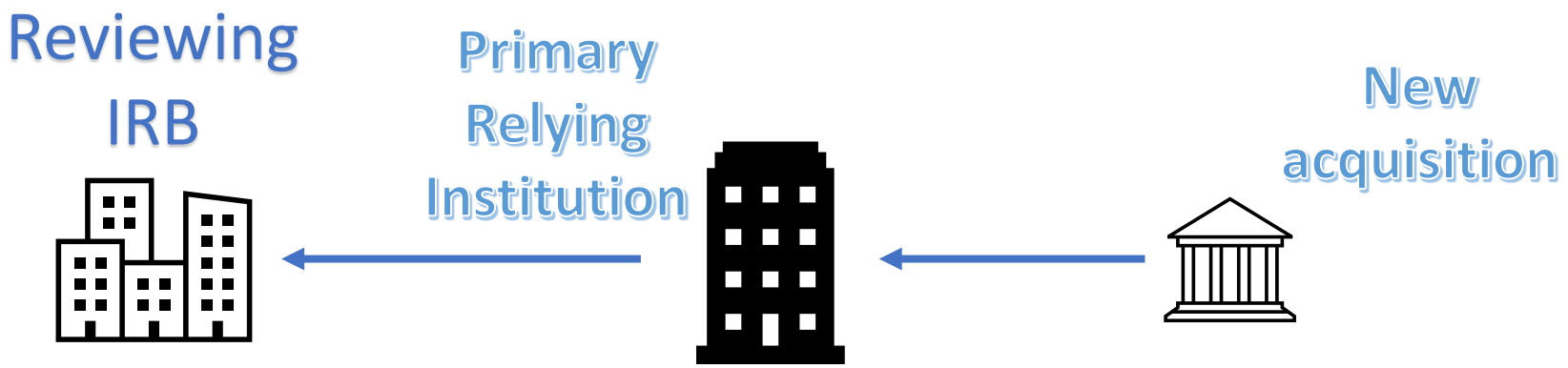
Existing Opportunities

Topic	Problem Statement	Best Practice Opportunity
Informed Consent Language	As IRBs have fewer places to insert institutional specific language, negotiations on "boilerplate language" have increased.	Use Part 1 and 2 consent templates; back all requirements by policy, practice, or guidance documents
"Duplicate IRB Reviews"	Research teams believe that institutional IRBs are duplicating an IRB review if "shadow file" is required	Educate research community on institutional responsibilities, establish unique SOPs unique, reimagine review workflows
Institutional Policies	Conflicting policies between relying and reviewing institutions can cause confusion for research teams (i.e., reporting obligations, IRB determinations)	Reconsider your local context and analyze what is unique about your institution which could be included
Technology Support	Electronic systems primarily support local IRB reviews	TBD – a lot of work is required here to overcome hurdles

Ceding Situation – "Standard"



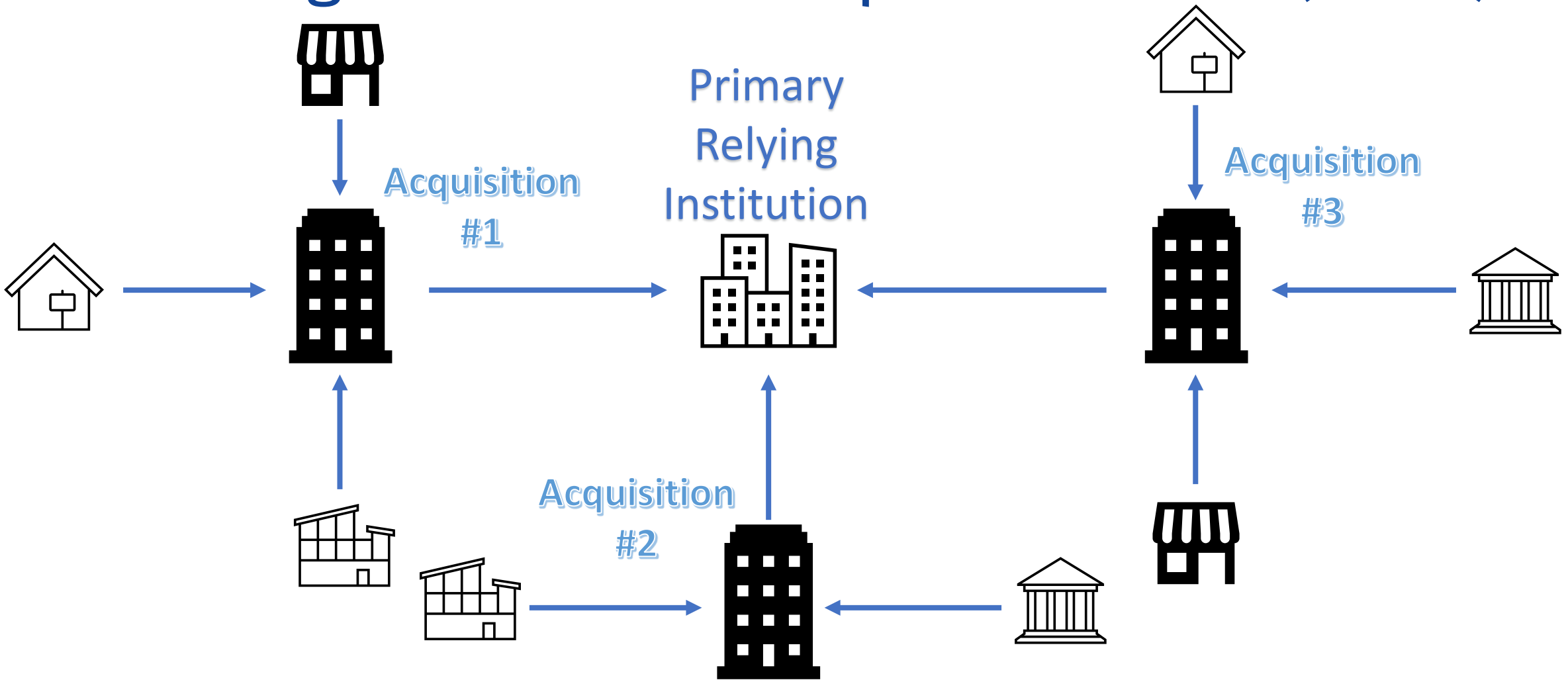
Ceding Situations – Acquisitions Era



- Healthcare and hospital acquisitions are on the rise and expected to continue[3]

- [3]https://www.chiefhealthcareexecutive.com/view/more-hospital-mergers-are-happening-and-more-may-be-on-the-way

Ceding Situations – Acquisitions Era (cont.)



Serial Ceding - Acquisitions

PROS

- Could extend research into the community via clinics, primary care offices, etc., if part of acquisitions
- May allow for more efficient use of resources
- Moving research into the community allows for potential participants who may not have the ability to be seen at traditional research institutions

CONS

- This increases burdens on site PIs and study teams to ensure training, education, and oversight are in place
- Is there clear transparency to the Reviewing IRB the relationships of Relying IRBs/Institutions??
- What burden does this create for the Reviewing and Relying IRBs/HRPPs (e.g., local context)

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Where are we going? What's ahead in the world of sIRB review?

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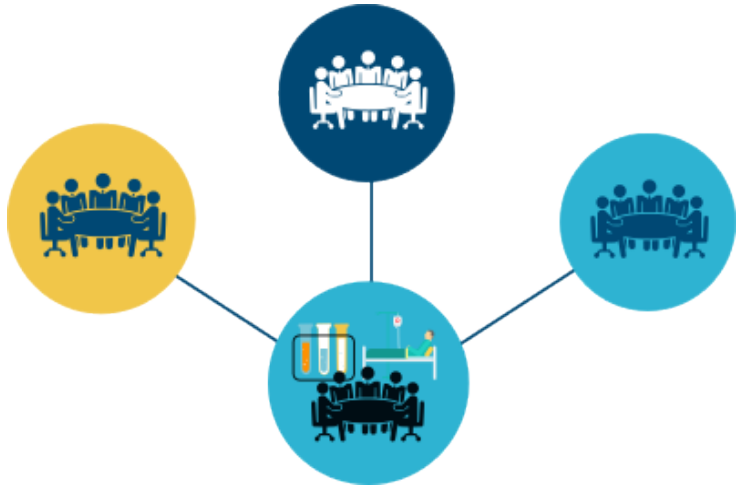
HRPP/IRB Models

HRPP has no internal IRB
Relies on External IRBs

HRPP has an internal IRB
Does not Rely on External IRBs



HRPP has an internal IRB
and Relies on External IRBs

Potential Change
FDA's Notice of Proposed Rule-Making

Protection of Human Subjects

- Would be effective 180 days after the final rule is posted
- Designed to align FDA rules with Revised Common Rule
- Required by the 21st Century Cures Act
- Proposed changes are substantively similar to Revised Common Rule (key information, consent elements, flexibility in continuing review, etc.)

Protection of Human Subjects and Institutional Review Boards

Cooperative Research

- Rule change would be effective 1 year after the publication date of the Final Rule
- **Requires any institution located in the United States participating in FDA-regulated cooperative research to rely on approval by a single IRB**
- Some exceptions proposed
- FDA approval of the chosen sIRB is not required

Institutional Review Boards; Cooperative Research

Goals of Proposed Rule Change

Harmonize with sIRB requirements of the Revised Common Rule → Increase efficiency, reduce regulatory burden and advance FDA-Regulated Research → Create a single focal point for FDA Inspections of IRBs for multisite research

- **Rule change would be effective 1 year after the publication date of the Final Rule**
- **New requirements would apply to research initially approved by an IRB after the effective date**

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Proposed Exceptions

- Where more than one IRB's review is required by law (same as Common Rule)
- Research involving highly-specialized FDA-Regulated Products
- Research on Drugs Exempt from the IND Regulations
- Research that meets the Abbreviated IDE requirements or is exempt from IDE requirements

Additional Exceptions under Consideration

- Studies with a small number of investigative sites (e.g. 5 or fewer)
- Studies where use of a single IRB is unable to meet the needs of specific populations.
- FDA authority to decide about appropriate exceptions on a case by case basis

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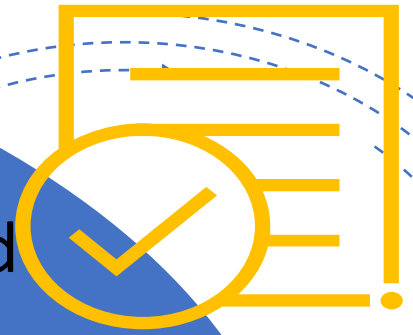
Institutional Impact of Proposed Rule Change



- Challenge in identifying which studies would qualify for an exception up front
- Reduced local IRB oversight of FDA-regulated research- need to increase oversight via other means (e.g. monitoring)
- Potential reduction in force including IRB members, staff, etc.

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Additional Regulatory Changes

Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions

Date of Issuance: June 16, 2023

Note: *This draft guidance is consistent with the 2018 Requirements (i.e., the revised Common Rule).*

Psychedelic Drugs: Considerations for Clinical Investigations

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written

Guidance Documents / Informed Consent

GUIDANCE DOCUMENT

Informed Consent

Guidance for IRBs, Clinical Investigators, and Sponsors

AUGUST 2023

Download the Final Guidance Document | Read the Federal Register Notice

Final

GUIDANCE DOCUMENT

Decentralized Clinical Trials for Drugs, Biological Products, and Devices

MAY 2023

Download the Draft Guidance Document | Read the Federal Register Notice

Draft | Level 1 Guidance

Not for implementation. Contains non-binding recommendations.

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FEDERAL REGISTER
The Daily Journal of the United States Government

PR Proposed Rule

Institutional Review Boards; Cooperative Research

A Proposed Rule by the Food and Drug Administration on 09/28/2022

GUIDANCE DOCUMENT

Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products

Guidance for IRBs and Clinical Investigators

SEPTEMBER 2023

Download the Final Guidance Document | Read the Federal Register Notice

Final | Level 1 Guidance

GAO Highlights

Highlights of GAO-23-104721, a report to

January 2023

INSTITUTIONAL REVIEW BOARDS

Actions Needed to Improve Federal Oversight and Examine Effectiveness

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Impact of Additional Regulatory Changes

Organizations may adopt local approaches (policy and practice) that impact sIRB considerations

New Mandatory "Local" consent requirements may be generated as new policies/regulatory requirements emerge

Processes are needed to understand how new rules impact existing/future studies subject to sIRB review

Where are we going: Remaining Relevant

- As more studies transition to external IRB reviews, how do IRB/HRPP Offices remain relevant, i.e., ensure the protection of human subjects?

- Questions that are important to answer:
  - What is your university's 5-10 year research plan ?
  - What is your current ceding portfolio; FDA-regulated portfolio?
    - Are you staffing this workload appropriately?
  - How would institution review research not required to be ceded?
  - How will institution ensure protection of human subjects?

Remaining Relevant: Moving from IRB to HRPP

- Theory of conservation of work[3]: that the total work of an isolated system remains constant

- What does this mean? Regulatory burdens for studies ceded to external IRBs is shifted onto study staff

- [3] Not an actual theory

Remaining Relevant: Moving from IRB to HRPP

Regulatory Burden on study teams with sIRB

- Communicating with multiple IRBs
- Using multiple IRB systems
- Understanding multiple IRB workflows
- Beholden to multiple IRB policies
- Unique study operational considerations

Moving from IRB to HRPP – Regulatory Liaison

- Similar to many Oncology research teams, can IRB staff serve as a regulatory team for study teams when ceding to an external IRB?
- Pros:
  - Relieve study teams of regulatory burden
  - Speak “IRB” with external IRB and translate regulatory considerations
  - Help ensure compliance with protocol, institutional requirements, and external IRB requirements

Remaining Relevant: Moving from IRB to HRPP

- Implementing QA/QI within IRB/HRPP Office
  - Not meant to be confused with external quality checks of IRB reviews
  - Examples:
    - Confirming FDA determinations are correct
    - Implementing second checks on certain submissions
    - Targeted assessments of institutional requirements

Where are we going: Regulatory Considerations

- Similar to what we need to currently consider (re: FDA NRPMs and NIH DMS Policy), regulatory changes will produce ripples in sIRB work
- What changes are coming… Artificial Intelligence
  - Automations of operations
  - Use of AI as tools (e.g., document creation)
  - What is an appropriate review of AI research?
- What opportunities exist to be proactive and build sIRB processes that are immunized against upheaval?

Thank You!

Questions?