The Brave New World of Single IRB Review

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Today’s Topics

The changing regulatory landscape

How to request single IRB review

Investigator vs. institutional responsibilities

Common scenarios
Working Definitions…

Single IRB Review – a legal arrangement that allows one IRB to review the research on behalf of other engaged institutions

Reviewing IRB – the IRB that fulfills the regulatory requirements of 45 CFR 46

Relying Institution – the institution that cedes IRB responsibilities to the reviewing IRB

The Old Way
The Changing Environment

- The Feds are encouraging IRB reciprocity agreements
  - *Single IRB review is becoming a frequent requirement for grant proposals*
  - *Proposed changes to the Common Rule*
- AAHRPP is supportive

New Possibilities
Human Research Protection Program (HRPP)

- HRPP guarantees appropriate IRB review
- Our assurance with the feds holds us responsible for all aspects of research conduct
- We are responsible to the feds for all research conducted by our faculty, staff or students regardless of the location

KUMC must grant permission to rely on an outside IRB

There’s a process
Let’s talk early
### What aspects can be ceded to an external IRB?

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<thead>
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<th>YES</th>
<th>NO</th>
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<td>IRB review</td>
<td>Education and training</td>
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<td>HIPAA</td>
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<td>RSC, IBC, Nursing</td>
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<td>Data security</td>
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<td>Budgets and contracts</td>
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<td>Reporting UP’s and non-compliance</td>
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### Current Arrangements

- CTSA regional partners: CMH, UMKC, St. Luke’s, KCUMB
- Greater Plains Collaborative – 12 sites
- NCI Central IRB
- US Oncology
- Neuronext, StrokeNet
- Western IRB
- Lawrence campus
- Wichita hospitals
- Multiple single-protocol agreements (e.g. distance learners)
When KUMC will be the relying institution

- Notify the IRB office
- Confirm that the type of research is one for which we are willing to rely
- Determine if the research is within the scope of an existing agreement
- Request permission through our eIRB system (truncated application process)
- Fulfill local requirements prior to release

Investigators need to know:

- What does the reviewing IRB require?
- How will you know their policies?
- Who will supply you with IRB-approved documents?
- Who gets notified in case of problems?
  - The Reviewing IRB
  - Your home institution
When KUMC will be the reviewing IRB

- PI submits through our eIRB system
- We work closely with the relying institutions to negotiate agreements
- Relying institutions supply “local context” information
- KUMC study team submits a delegation of duties log for all study team members
- Our IRB issues consent forms for all sites

Investigators need to know:

- Are there any special requirements with state law or the local institution?
- Will there be any variability in study implementation?
- Who will be your project manager?
- Who will be the point of contact at each site?
- How will you train study personnel?
- How will you monitor compliance?
Three Common Scenarios

1. You’ve designed a study that involves multiple institutions, each of which has an IRB
2. You’re a collaborator on external research
3. There are non-KUMC personnel working on your research

Scenario #1 – You’ve designed a study that involves multiple institutions, each of which has an IRB
Key Question:

Which IRB will take the lead?

What you should do…

- Let’s talk early
- The grant proposal or IRB reliance agreement may stipulate who is the reviewing IRB
- Either way, we will coordinate with the other IRBs
Scenario #2: You’re a collaborator on research sponsored by another university

**WARNING:** Regulatory Jargon ahead

**Key Question:** Are we engaged??
Is KUMC engaged in human subjects research on this project?

**YES**
- Obtain informed consent
- Administer study procedures, drugs, etc
- Conduct interviews, focus groups
- Analyze identifiable data or specimens

**NO**
- Distribute recruitment materials
- Provide professional services
- Only release clinical data or specimens
- Analyze de-identified research data or specimens

If your research activities cause KUMC to be engaged, the Feds give us two choices:

1. The KUMC IRB can review the project
   -- OR --
2. We can negotiation an agreement to rely on the other institution’s IRB review
What you should do…

- Let’s talk early
- Find out what the lead PI is planning
- If KUMC is engaged, we’ll contact the reviewing IRB and arrange reliance if they are agreeable
- Make sure you are covered before you start working on the project

Scenario #3: There are non-KUMC* personnel working on your research

*Non-KUMC = individuals who are not faculty, staff or students of KUMC, KUSM-W or the Health System
Key Question:

Is their employer engaged?

What you should do…

- Let’s talk early
- If their employer is engaged, the employer has the same two choices (review or rely)
- Projects with federal funding have extra requirements
- Unaffiliated community members can be accommodated
Current Challenges

- Variability on reliance agreements
- Most institutions are still learning
- Education for study teams
- Resources needed for coordination
- QA monitoring
- eIRB accounts for external personnel

Yes, it’s a bit complicated…
There are benefits to Single IRB Review

- Streamlined process for full-board reviews
- May be required for grant applications
- Patients can get faster access to new therapies

In Summary

- Single IRB reviews will only increase
- This is a brave new world
- Let’s talk early
- Let’s talk often
- We can help you succeed
KUMC Resources
http://www.kumc.edu/human-research-protection-program/institutional-review-board.html

KC IRB Office  (913) 588-1240
Wichita IRB Office  (316) 293-2610