Disclosures

Nothing to disclose and all opinions are my own

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Agenda

- What is flexibility?
- Case study - Impact on workload
- New common rule – what this means for flexibility and single IRB
- How to assess what is important and what to change

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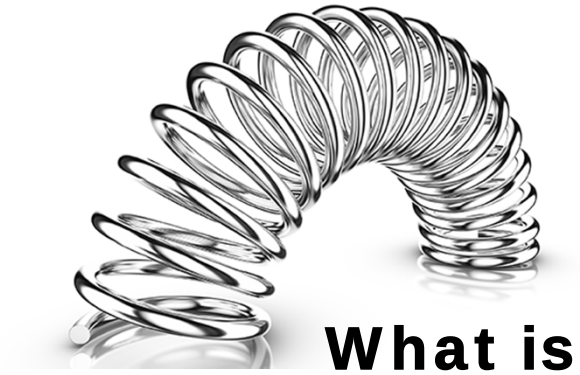

What is flexibility?

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Paradigm shift

From dictating requirements to allowing researchers to work within a framework that both parties have mutually agreed are acceptable.

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Flexibility does not….

- Reduce protection of human subjects
- Reduce requirements for reporting
- Reduce or remove other regulatory requirements (e.g. HIPAA)

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What flexibility does…

- Allows for new administrative options to review minimal risk research.
- Increase our ability to adjust to new demands.
- Allows staff to engage in more education, outreach, and auditing.
- Reduce turn-around times to approval.

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The Process

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Impetus for flexibility

- Many very similar projects being submitted from the same unit – How to reduce that burden?
- Flexibility Coalition http://oprs.usc.edu/about/initiatives/flex/
  - Platform for schools to share flexible policies and options

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The Box

- "Uncheck the Box" - Done in 2010
- Means reporting to federal agencies is eliminated for studies that are not federally funded.
- Means common rule as we know it does not apply.

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The Policy

- Establish a Flex Policy
- Outline Exclusions/inclusions to Flexibility
- Develop Standard Operating Procedures (SOPs)

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Key Policy Elements

- New exempt categories
- Renewals are 2 years
- Expansion of expedite categories
- Expansion of vulnerable population categories
- Expansion of engagement
- Reporting requirements reduced

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The Oversight

- Develop Standard Operating Procedures (SOPs)
- Audit/Monitor Flexed Studies

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Impact on workload

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The numbers

2012		2015
46 avg calendar days for IRB approval	→	**17.9** avg calendar days for IRB approval
8 Staff	→	**5** Staff
4 IRB meetings/Month	→	**2** IRB meetings/Month

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Volume

Number of projects reclassified to flexible exempt categories

Flex 7 (Benign Interventions)=77

Flex 8 (Data) = 360

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Other benefits

- Allowed staff to conduct not-for-cause audits of 68 studies
- Increased staff time spent on outreach – 100 additional education sessions
- Assist other compliance units
  - COI office for processing award holds and training validation
  - Privacy office for DUA checks
  - Sponsored project data cleanup of over 1500 awards linked to IRB protocols

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2018 Rule

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2018 Rule

- Incorporates flexible options directly into rule.
- Requires single IRB review.

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Changes that are flex

- Identification of things that are not research
- Increased exempt review categories (but requires limited IRB review by an IRB member)
- Continuing review disappears (unless required by IRB)
- sIRB (but need to still keep track of locally)

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Vulnerable Populations

- Subparts still remain. No change.

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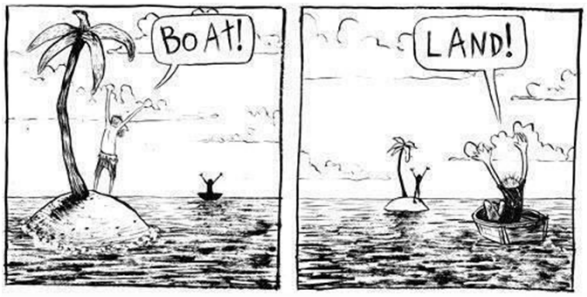
Single IRB



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Perspective

- 2012 – 9.0% of workload
- 2016 – 17.0% of workload

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Local context

- Adherence to local policy
- Conflict of Interest
- Special considerations for vulnerable populations
- Who's the PI and staff – do some need to be watched more closely?
- Reporting requirements

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How to assess what is important to your organization?

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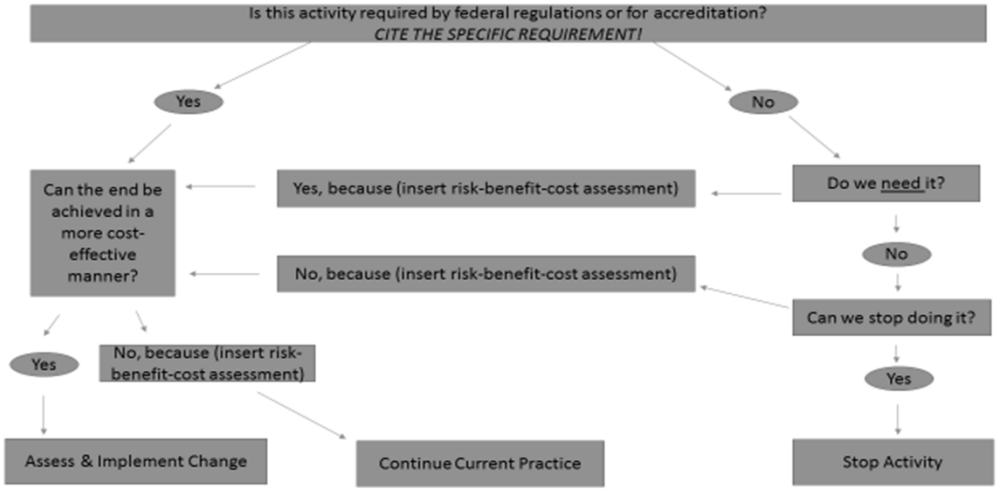
Roadmap for success



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Key stakeholders

- Don't make changes in a vacuum – involve key stakeholders!
- Hold town halls or workgroups.
- Accept feedback and criticism.
- Ownership is the institution, not the individual.

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How did we do it?

- Generalize the IRB so projects do not have to wait until next meeting of that panel.
- Does the IRB application make sense to researchers?
- Do all the questions on the application serve a purpose?
- Can the workflow, from intake to final approval, be changed?

How did we do it?

- Are all the requirements being asked based in the regulations, institutional policy, or 'just because we have always done it that way'?
- Can and should the institution consider ways to put less burden on less risky projects? Think flexibility!

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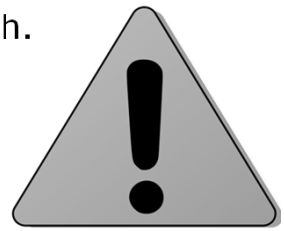
Caution

- Flexibility requires additional communication with investigators on requirements.
- Need stakeholder support and assistance.
- Must keep track of flexible projects.
- Must be aware when funding changes!
- Not applicable to FDA regulated research.



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Last thought

It's all in how you arrange the thing... the careful balance of the design is the motion.

Andrew Wyeth

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