Finding flexibility in the regulations
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Disclosures

Nothing to disclose and all opinions are my own

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
What is flexibility?

Paradigm shift

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

Flexibility does not....

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

The Process

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
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.

The Policy

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

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
The Oversight

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

Impact on workload

The numbers

<table>
<thead>
<tr>
<th>Year</th>
<th>Avg Calendar Days for IRB Approval</th>
<th>Staff</th>
<th>IRB Meetings/Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>46</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>2015</td>
<td>17.9</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>
Volume

Number of projects reclassified to flexible exempt categories

Flex 7 (Benign Interventions) = 77
Flex 8 (Data) = 360

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 DUJA checks
  • Sponsored project data cleanup of over 1500 awards linked to IRB protocols

2018 Rule
2018 Rule

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

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)

Vulnerable Populations

- Subparts still remain. No change.
**Single IRB**

**Perspective**

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

**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
How to assess what is important to your organization?

Roadmap for success

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.
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!

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,
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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