Finding flexibility in the regulations
Mariette Marsh, MPA, CIP
HCCA 2017 Baltimore, MD
June 5, 2017

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

Is this activity required by federal regulations or for accreditation? *CITE THE SPECIFIC REQUIREMENT*

- **Yes**
  - Can the end be achieved in a more cost-effective manner?
    - **Yes**, because (insert risk-benefit-cost assessment)
      - **Yes**, because (insert risk-benefit-cost assessment)
        - **Assess & Implement Change**
    - **No**, because (insert risk-benefit-cost assessment)
      - **No**, because (insert risk-benefit-cost assessment)
        - **Stop Activity**
  - **No**, because (insert risk-benefit-cost assessment)
    - **Do we need it?**
      - **No**
      - **Can we stop doing it?**
        - **Yes**
        - **Stop Activity**
      - **Yes**
        - **Continue Current Practice**

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

CONTACT INFORMATION

Mariette Marsh, MPA, CIP
marshm@email.arizona.edu
(520) 626-7575

www.rgw.arizona.edu