Introducing Flexibility in Practice While Maintaining Regulatory Compliance

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How much flexibility do you want?
Pros and Cons of Flexibility

- **Pros:**
  - Advance Research
  - Scientific Design Fit
  - Ethical Fit
  - Pragmatic Solutions
  - Compliance

- **Cons:**
  - Variability Inefficiency
  - Varied Outcomes
  - Gaming the System
  - Level of Sophistication
  - Compliance
Interpretable Terms (Scope)

- Supported
- Research
- Systematic Investigation
- Generalizable Knowledge
- Human Subject
- About Whom
- Intervention
- Interaction
- Private Information

- Normal Educational Practices
- Educational Tests
- Survey or Interview Procedures
- Public Behavior
- Existing
- Public Benefit
- Engaged [in research]
Interpretable Terms

- Equivalent Protections
- Legally authorized representative
- Written procedures
- Prompt reporting
- Unanticipated Problems
- Serious or continuing noncompliance
- Suspension or termination of IRB approval
- Joint review arrangement
- Minimal Risk
Interpretable Terms (IRB/Approval)

- Sufficiently Qualified
- Knowledgeable about and experienced in working with these subjects
- Scientific/Nonscientific
- Not otherwise affiliated
- Conflicting Interest
- Convened meeting

- Risks are minimized
- Benefits
- Reasonable risks
- Risks of research
- Equitable (selection)
- Informed Consent
- Vulnerable population
- Vulnerable to Coercion
- Vulnerable to Undue Influence
Interpretable Terms (Consent)

- Sufficient opportunity to consider whether or not to participate
- Language understandable to the subject
- Exculpatory language
- Purposes of the research
- Reasonably foreseeable risks
- Benefits to subjects
- Alternative procedures
- Significant new findings
- Adversely affect rights and welfare
- Practically
- Additional pertinent information
- Signed by the subject
HHS supported, conducted, or covered by an assurance declaration

36% do not check the box
30% check the box applying Subpart A
34% checking the boxes applying Subparts A, B, C, and D.
Designation of the Reviewing IRB(s)

- Institution’s own IRB (s)
- ‘Borrowing’ an IRB
- ‘Renting an IRB’
- Cooperative Arrangements for IRB review, including central/single IRB review of multi-site studies
Reviewed by Convened Board

- Physical/Virtual Meeting
- Number of Members
- IRB Staff as Members
- Alternate Members
- Review Procedures
- Approval with Conditions
- Approval Period
Obtaining Expertise/Information

IRB members

Investigators

Local IRB members

Consultants

Search

Research

Community Representatives
Expedited Review -

• is applied by the Chair or IRB member(s) appointed by the Chair;
• uses the same review criteria as full board review for initial and continuing review;
• can approve or modify research activities, but not disapprove them; and,
• applies to minimal risk activities in the approved HHS/FDA list of categories.
Managing Exempt Research

• Who decides if an activity is exempt?
• How are the exemption categories interpreted?
• Does the Institution approve/disapprove exempt research?
• What happens in exempt research?
What is “minimal risk”?

“Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (.102(i))
Three alternative standards of the risks of harm or discomfort

- Routine Physical Examinations or Tests
- Routine Psychological Examinations or Tests
- Daily Life
Waiver/Alteration of Informed Consent (or Parental Permission/Assent)

- Public Benefit Program Research (.116(c))
- General Research (.116(d))
- Research Involving Children (.408(c))
Documentation of Informed Consent may be waived if:

- The only record linking the subject and the research is the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; or,

- The research is no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context. (.117(c))
What are “reasonable” risks?

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

Section .111(a)(2)
What are “minor changes”?

An IRB may use the expedited review procedure to review either or both of the following:

(1) ..... 

(2) *minor changes* in previously approved research during the period (of one year or less) for which approval is authorized.

Section .110(b)(2)
What does the IRB application say?

How is the research activity described, and at what level of detail?
Finding the Right Level of Flexibility