Finding Flexibility in the Regulations

Judith Birk, JD,

Director, IRBMED

University of Michigan

Michelle Feige, MSW, LCSW-C

Executive Vice President

AAHRPP

University of Michigan Medical School

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Session Overview

- Define regulatory flexibility
- Examine the benefits
- Describe opportunities offered by the regulations
  - Within the Common Rule
  - External to the Common Rule
- Consider an implementation toolkit

Primary Tenet

OHRP and AAHRPP encourage institutions to utilize the flexibilities found in the HHS regulations at 45 CFR part 46.

Defining Regulatory Flexibility

Sources of Flexibility in the Regulations

- Federalwide Assurance (FWA)
- Applicability of the Regulations
- IRB Review Procedures
- Informed Consent – Alterations and Waivers

Federalwide Assurance: Requirements

- Defines an institution's relationship with OHRP
- Applies when an Institution is engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Common Rule (Subpart A), unless the research is otherwise exempt.
  - **Required:** Compliance with Subpart A for all research conducted or supported by Common Rule agencies
  - **Required:** Compliance with all subparts of 45 CFR part 46 for all research conducted or supported by HHS

Federalwide Assurance: Options

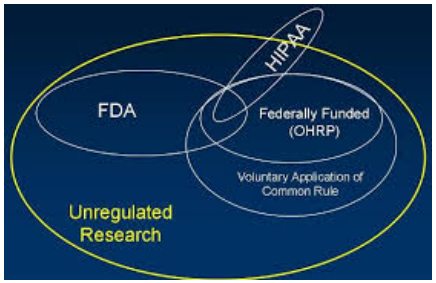
- Scope of FWA
  - **Optional**: Follow Subpart A for all research, regardless of funding source
  - **Optional**: Follow all subparts of 45 CFR part 46 for all research, regardless of funding source

- Limiting FWA to Federally conducted or supported research allows additional flexibility

FWA Flexibility in 4(b)

- (b) *Optional for U.S. institutions:* This Institution voluntarily elects to apply the following to all of its non-exempt human subjects research regardless of the source of support, except for research that is covered by a separate assurance issued by another U.S. federal department or agency that has adopted the Common Rule:
- **[ ] *The Common Rule* (see section 3 of the Terms of the FWA for a list of U.S. federal departments and agencies that have adopted the Common Rule and the applicable citations to the Code of Federal Regulations)**
- **[ ] *The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46***

Leaving 4(b) Unchecked: What Does it Mean?



- Provides flexibility to create new models of institutional practice for review and oversight of qualifying human subject research

- Institutional policy will delineate
  - When federal regulations will still apply
  - When equivalent protections will apply

Why *Not* Use Sources of Flexibility?

- Unaware of regulatory flexibility
- Fear of making the wrong decision
- Fear of OHRP or other compliance oversight
- Mistrust of reviewers or investigators

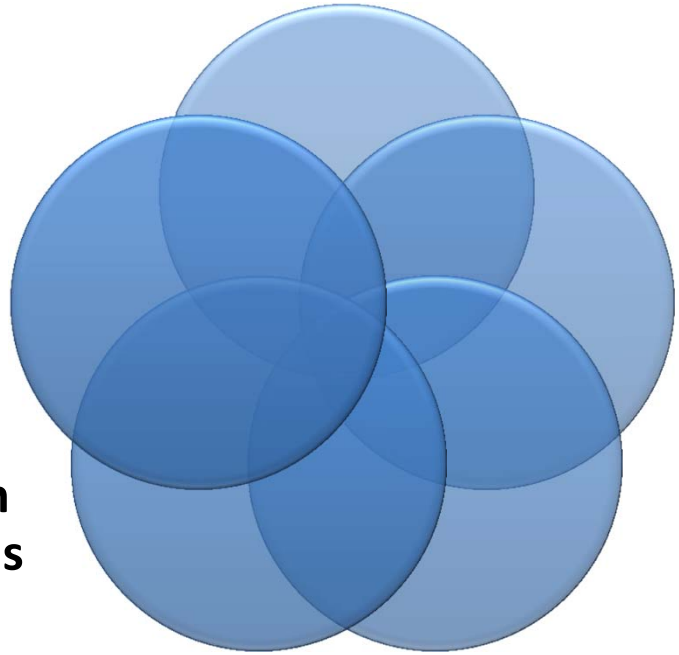
The Benefits of Regulatory Flexibility

Regulatory Flexibility Permits

* Utilization of available regulatory parameters and endpoints

*Development of procedures with local relevancy

*Appropriate allocation of review efforts within the IRB



*Demonstrates self-evaluation and continuous improvement efforts

*Maintenance of human subjects protections while enhancing review models

Everyday Translation

- Regulatory endpoints are not always a good fit especially for low risk activities
- Shrinking resources
- Increasing regulatory burden
- Growing volume of research

Regulatory Opportunities: Flexibility within the Common Rule

Definitions

- Use the regulatory definitions of “research” and “human subjects” respectively at 45 CFR 46.102(d) and (f)

- Activities that do not meet the definitions of human subjects research need not be reviewed by the IRB

Flexibility:
Exempt Reviews

Categories of **Exempt** Research*

1. Normal educational practices in established educational settings
2. Educational tests, surveys, interviews, or observation of public behavior -unless identifiable & sensitive**
3. Research on elected or appointed public officials or candidates for public office
4. Research using existing data, if publicly available or recorded without identifiers
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

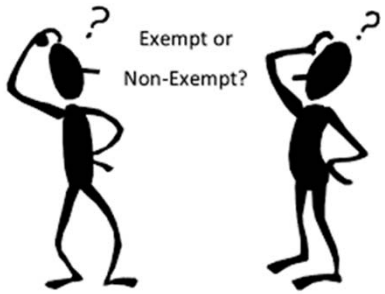
§46.101(b)(1-6)

* Exception for prisoners

** Exception for children

IF DETERMINED AS EXEMPT, NO FURTHER REVIEW NEEDED!

Determination of Exemption

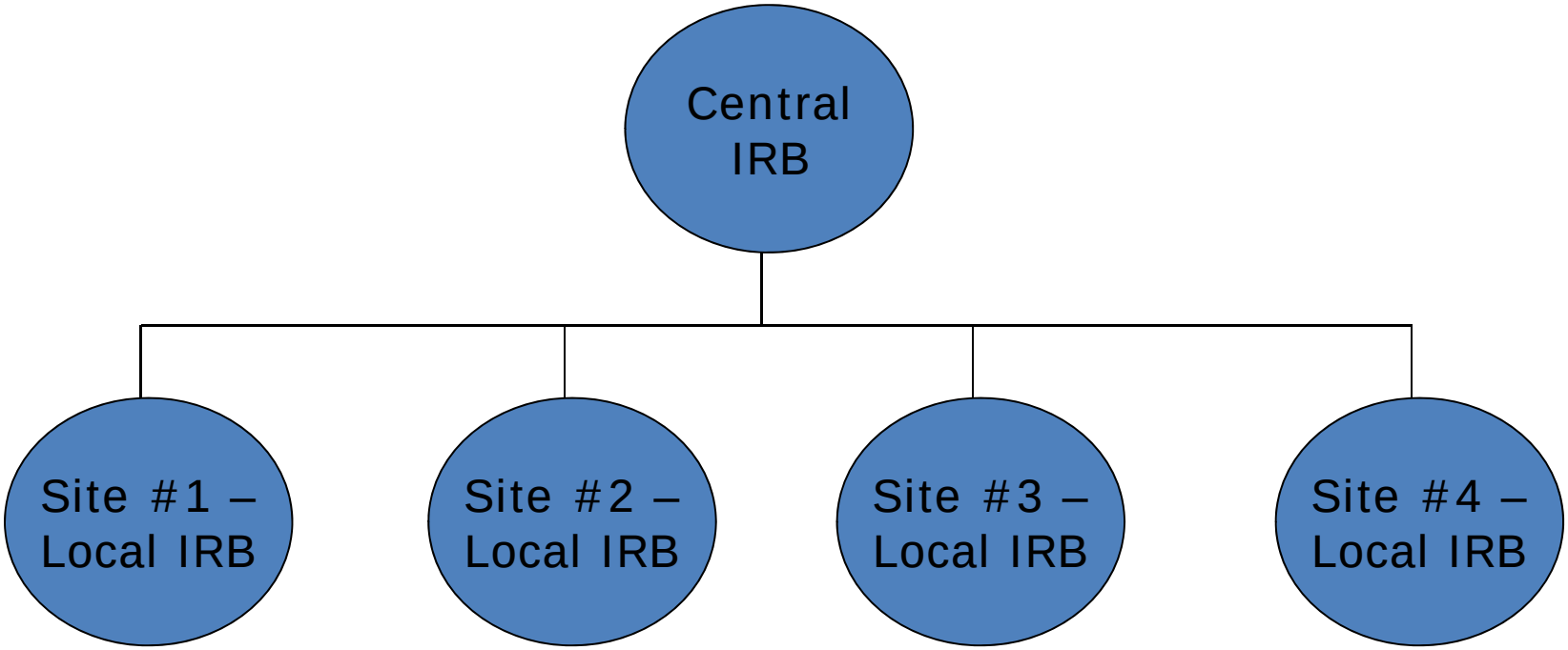


- Regulations do not specify who may make exemption determinations …so, YOU CAN DECIDE (aka FLEXIBILITY!)
  - Must be trained and qualified
  - Not the investigator or members of the research team

- FAQs on exemption determinations at: http://www.hhs.gov/ohrp/policy/exemptfaqsmar2011.pdf
- Exemption category should be documented

Flexibility:
IRB of Record Arrangements

General Model



Reliance Relationships

- Academic
- Commercial / Independent
- Collaborative (IRBShare)

Flexibility:
Expedited Review Procedures

Expedited Review

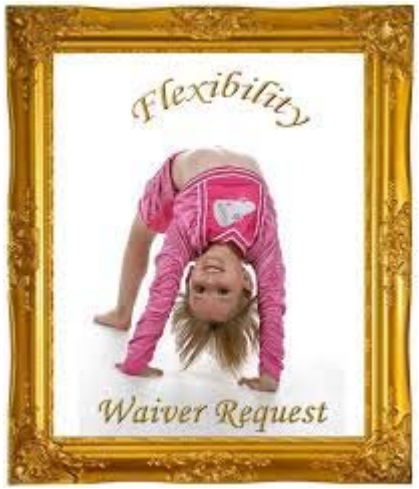
An IRB may use expedited review for

- Minimal risk research on list of eligible categories (63 FR 60364-60367)
- Minor changes in previously approved research (45 CFR 46.110)

Expedited Review

- Carried out by IRB chair or one or more experienced IRB members
  - May have alternate member be expedited reviewer
  - May have assistance from consultant
- Reviewers can exercise all of the authorities of the IRB except disapproval
- Mechanism to inform all IRB members of research approved under expedited review

Flexibility:
Informed Consent -
Alterations & Waivers



Two Types of Consent Forms are Permissible:

1) Written consent document that includes:

- Basic elements of informed consent
- Any applicable additional elements

OR

2) Short form which states:

- That the elements of informed consent have been presented orally to the subject

Flexibility:
Alter or Waive Informed Consent

Provisions for waiver or alteration:

- Consistent with §46.116(c) or (d)
- Waiver of child assent & parental permission - §46.408 (subpart D)
- Secretarial waiver §46.101(i) – e.g., research conducted in emergency setting

Informed Consent – Alteration or Waiver

If the IRB finds *and* documents that:

- No greater than minimal risk,
- Will not adversely affect rights & welfare of subjects,
- Research could not practicably be carried out without the waiver or alteration, AND
- When appropriate, subjects will be "debriefed" after participation

§46.116(d)

Flexibility:
Waive *Documentation* of IC

IRB may waive documentation if it finds either:

- Consent form only record linking subject and research; *AND*
- Principal risk from breach of confidentiality.

OR

- Minimal risk research; *AND*
- Research procedures do not require written IC if done outside research context

§46.117(c)

Quick Quiz:

Do the regulations under subpart D require that assent be documented?

A. Yes
B. No

NO!!!

- “Adequate provisions”
- Can be verbal
- Can be written
- Should be tailored to the research and age/maturity of the subject

Flexibility Opportunities: External to the Common Rule

Currently Used Flexibilities

- Lengthened approval periods
  - Two year (or greater) approvals
- New exemption categories
  - Research with identifiable data
  - Student research
- New expedited categories
  - Delineate specific clinical procedures for minimal risk research

Additional Flexibilities: Broad-Scope Approvals

- Ranges or classes of populations
- Ranges of compensation to subjects
- Pre-approved survey instruments or classes of surveys
- Categories of questions for focus groups
- Ranges of allowable stimuli for perception or psychology experiments

Flexibility:
A Toolkit for Implementation

Flexibility Checklist

- ✓ FWA
- ✓ Institutional support
- ✓ Determine objective
- ✓ Develop equivalent protections / policies
- ✓ Assess workflow modifications
- ✓ Educate to the change
- ✓ Monitor and track the flexibility project

Building Support for Flexibility

- Meet with Stakeholders (IRB Staff, researchers)
- Discuss challenges, inefficiencies
- Discuss potential outcomes
  - Reduction of unnecessary administrative regulatory burdens
  - Resource reallocation within the IRB
  - Enhanced satisfaction with the IRB
  - Consider any quick wins
- Outline the process
  - Develop an impact statement
  - Plan for institutional roll-out
  - Develop measurements for success

Building Flexibility Options

Significant impact in a simple workflow	• Eliminate regulatory excess that is not protecting human subjects
Ease of administration	• Minimal re-programming of the (electronic) IRB application • Uncomplicated policy development / materials/ monitoring • Short implementation time-line
Uncomplicated process for investigators and study teams	• Simple education • Ease of implementation

Defining Equivalent Protections

Review of the research and subject protections are accomplished by means of equivalent mechanisms.

Modified Practice / Review

- Define opportunities outside of 45 CFR 46

Reduce Regulatory Excess

- Describe procedures and process

Application of Ethical Standards

- Utilize the best strategies to protect subjects (Federal, Other)

Closely Evaluate

- Risk level (consider minimal risk only)
- Vulnerable populations
- Nature of research interventions with subjects
  - Clinical
  - Behavioral
- State and local laws and institutional policies

Exclude Some Research

1. Federally supported (adhering to the Common Rule)
2. Under FDA jurisdiction
3. Held to federal regulations by contract or other legal obligation
4. Holds a Certificate of Confidentiality

Monitoring Flexibility Efforts

- Conduct periodic monitoring
- Assess against applicable regulatory requirements in a non-flexibility environment
  - Evaluate against normal procedures
- Evaluation of equivalent protections
  - Do they maintain subject safety?
  - Were efficiencies realized?
  - Additional outcomes noted?
  - Are changes necessary?
- Should monitoring be continuous?
- Assessing for federal funding (anticipated or secured)

Additional Considerations

Research was initially sponsored using federal funds, but now has no federal sponsorship.

Q: Does the study qualify for flexing?

Yes

A student is funded by a federal training grant, but the research they are conducting is not federally funded.

Q: Does the study qualify for a demonstration?

No

Flexibility Resources

Flexibility Coalition:

https://oprs.usc.edu/initiatives/flex/

University of Michigan Demonstration Initi

http://www.hrpp.umich.edu/initiative/demonstrations.html

Flexibility Checklist:

https://oprs.usc.edu/initiatives/flex/

Thank you to:

Susan Rose, PhD

University of Southern California

Slides and Consultations

Questions?