Creative Flexibility Opportunities

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I. Beyond the Common Rule: Establishing a Flexibility Policy

Setting Flexibility Policy Framework
- Identify projects not subject to the Common Rule
- Assure equal protections
- Set policy limits around inclusion/exclusion
  - Inclusions to Flex Policy (USC model):
    - Studies no greater than minimal risk
    - Studies with no federal funding
    - Equivalent protections commensurate with risk level
  - Exclusions to Flex Policy (OSU model):
    - Studies involving clinical interventions\(^1\)
    - Ancillary reviews (radiation safety, biosafety, conflict of interest, Cancer Center Clinical Investigations Committee)
    - Funding (exceptions may apply for non-federally funded research)
    - Research funded or otherwise regulated by a federal agency that has signed on to the Common Rule, including all agencies within the Department of Health and Human Services
    - Classified research (research procedures and/or results are legally knowable only by individuals with United States government security clearance)
    - Studies with FDA-regulated components

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\(^1\) For the purposes of this policy, clinical intervention is defined as one that is intended to change or assess a health-related processes and/or endpoint. Examples include the use of drugs, dietary supplements, devices, blood draws, imaging (e.g., DXA, x-ray), delivery systems (e.g., telemedicine, face-to-face), diet, cognitive therapy, exercise, and any intervention that includes treatment, prevention, or diagnostic strategies.
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- Projects where a student is paid/supported from a federal training grant or otherwise paid/supported directly from the Faculty Advisor’s federal funds
- Studies with contractual obligations or restrictions that preclude eligibility in this policy
- Studies using prisoners as subjects
- Studies seeking or obtaining Certificates of Confidentiality
- Studies required to register to ClinicalTrials.gov

Develop Flexibility Policies / SOPs
Flexibility policy should meet local needs and restrictions:
- Customize SOPs, as site requires (Socio-Behavioral Research vs. Biomedical)
- Flex policy can be integrated in IRB Policies and Procedures (e.g., revise applicable sections) or be a stand-alone policy
- Establish policy to monitor compliance of flexed studies annually
- Update/add additional flex as opportunity arises (e.g. New Rule)

Metrics for Auditing/Monitoring of Flexed Studies
Implement mechanisms and written metrics to routinely monitor and annually audit all/percentage of flexed studies:
- Verify funded studies have not been flexed
- Verify studies scope of work did not change
- Report to HRPP

II. Flexibility with Subparts (A, B, C, D)

Subpart A
- Create new minimal-risk review category or establish exemption categories for minimal risk activities not addressed in exempt/expedited regulations.

Examples:
  - Research that does not conform to a specific exempt category under 45 CFR 46

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2 Incidental incarceration may not require subpart C regulations. The subjects continued participation is under the investigators overall responsibility to protect the rights and welfare of subjects.
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- online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk
- behavioral games
- studies requiring performance of tasks that incur no risk

  - Research where activity is limited to study of existing or prospective identifiable data
    - medical record reviews where data is extracted from records
    - data analysis of information already collected from court records
    - data/specimens collected during a previous research study

- Create short, smartform application for chart reviews
- Create short, smartform application for use of de-identified datasets

Subpart B: Pregnant Women, Fetuses, and Neonates
Opportunities for flexibility with review of research involving pregnant subjects:
- Exploit flexibility as FDA regulations have no Subpart B
- Obtain permission from the mother only (for neonates/fetuses)
- Consider flexibility for social-behavioral research
- Consider not applying Subpart B to all minimal risk research

Subpart C: Prisoners
Opportunities for flexibility with review of research involving prisoners as subjects:
- Exploit flexibility as FDA regulations have no Subpart C
- Consider flexibility for social-behavioral research
- Do not apply Subpart C to subjects who become incarcerated after study enrollment
- Expand definition of who is not a prisoner (house arrest, community service, parole, court-ordered treatment)

Subpart D: Children
Opportunities for flexibility with review of research involving children as subjects:
- Only require signature of one parent for unfunded studies, regardless of risk
- Do not require written assent

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III. Flexibility with IRB Submission and Review

Flexibility as a strategic approach to all IRB reviews:

- Review each protocol at the least-restrictive level of review
- Evaluate risks in terms of probability and magnitude
- Take advantage of all FDA discretionary enforcement (e.g., in vitro device studies)
- Create IRB meeting minutes that are shorter, faster, and regulatory compliant

Expand IRB Staff Duties

Empower IRB staff to:

- Be an IRB member/ alternate
- Verify minor contingencies are satisfied
- Perform all non-committee functions
- Handle all regulatory issues that do not require an IRB
- Be designated as Expedited Reviewer/ limited IRB Reviewer
- Be designated as Exempt Reviewer
- Perform pre-review to verify applications are complete and address potential obstacles to approval

IRB Application

Integrate flexibility into the IRB application:

- Assure the electronic/paper IRB application incorporates flex policies
- Assure funding questions appear early in application to identify flex-eligible projects and avoid unnecessary questions applicable to funded projects
- Assure Conflict of Interest questions appear early in application to address the conflict or re-route application based on institutional practice
- Minimize the submission form for ceded studies

Contents of IRB Submissions

Encourage flexibility from investigators:

- Allow generic descriptions of research staff so amendments to the study are not necessary (e.g., a registered pharmacist will dispense study drugs)
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- Allow investigators to write protocols in more general terms so that minor modifications to research are not necessary. Examples:
  - Range of subjects to accrue
  - Ranges of compensation instead of specific dollar amount
- Create generic protocols for common research activities where urgency exists

**IRB Automation**
Use electronic tracking systems, when possible:

- Automate/simplify how education requirements are tracked (e.g., automatic uploading of human subjects research education)
- Automate a "personnel change" button (excluding Principal Investigator and individuals who conduct consent) in place of amendment submissions

"Not Human Subjects Research" (NHSR)
Establish policy to exclude projects from IRB review that do not meet the federal definition of Human Subjects or Research:

- Create brief online application to verify NHSR projects and provide documentation of NHSR determinations to researchers
- Publicize/make investigators aware of NHSR, especially students

**Flexibility with HIPAA**
Implement, when possible:

- Have IRB serve as Privacy Board
- Use boilerplate, fill-in-the-blank HIPAA Research Authorization forms approved by Compliance Office that require de minimus information
- Create short, smartform application for research using limited datasets

**Innovative IRB Models**
Streamline the composition of the board:

- Establish a flexible pre-review IRB model that consists of smaller number of regular IRB members offset by larger alternate member roster, utilizes consultants for scientific expertise and meets more frequently with few items per agenda

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- Establish a Rapid Activation IRB structured to address minimum regulatory requirements in reviewing compassionate use requests, emergency/urgent projects and protocols that have a defined/limited study activation window

Engagement in Research

- Do not consider "engagement" for exempt studies
- Relax engagement requirements
- Do not require formal inter-institutional IRB agreements when both sides agree

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