Human Research Compliance

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Discussion Topics

- IRB Regulations and Structures
- Common Rule & Single IRB Use
- Non-Compliance in Human Research
- Remediation Strategies

IRB REGULATIONS AND STRUCTURES

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Regulatory Landscape

Research involving human volunteers requires review and approval by an IRB.

- Department of Health & Human Services
  - 45 CFR 46 – "The Common Rule"
- Food & Drug Administration
  - 21 CFR 50, 56, 312, 812
- Federalwide Assurance: Institutional Promise

Do you know what is regulated? Does your workforce?

IRB Structures

INSTITUTIONAL IRBs

- Common Model in Academic Medical Centers
- Local IRB review provided within the institution

RELIANCE ON "EXTERNAL" IRBs

- More Common Model in Community Hospitals/Independent Physician Practices
- Local IRB review provided outside the institution
- Trending, even in institutions with their own IRB

Human Research Protection Program

The human protection program is in place to ensure the rules are followed, regardless of IRB structure.

- Partners with IRB in review; communicates local context considerations to external IRBs
- Monitors research conduct for compliance with regulations, IRB requirements
- May work with IRB to report non-compliance to the Institutional Official/Federal Agencies

COMMON RULE & SINGLE IRB USE

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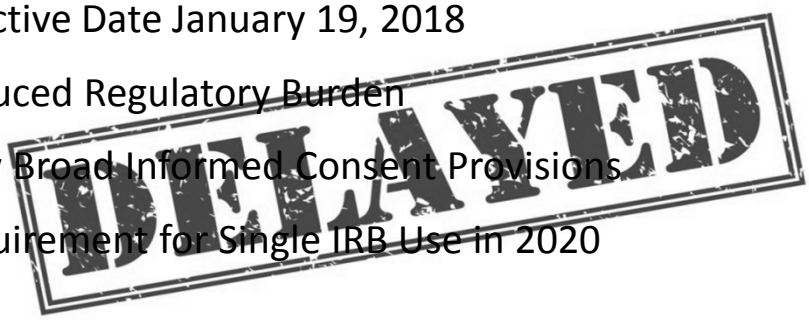
Common Rule Revisions

- Effective Date January 19, 2018
- Reduced Regulatory Burden
- New Broad Informed Consent Provisions
- Requirement for Single IRB Use in 2020



New Effective/Compliance Date: July 19, 2018 (for now!)

Single IRB Use

Common Rule Provisions

- Requires Single IRB for domestic multi-site research funded by the US DHHS and other agencies that follow the common rule
- Effective Jan 19, 2020

NIH Single IRB Use

- Effective January 25, 2018
- Applies to NIH funded non-exempt, multi-site research conducted at two or more domestic sites where each site runs the same protocol

Responsibilities

Reviewing IRB

- Maintain IRB registration, compliant membership, records, and SOPs
- Review study/consent to ensure meet regulatory criteria for approval
- Conduct post-approval IRB reviews (annual reviews, amendments, etc.)

Relying Site

- Maintain FWA, review local context, investigator qualifications, etc.
- Ensure consent has local information (e.g., injury language, HIPAA)
- Conduct on-site monitoring; report issues to IRB as needed
- Coordinate ancillary reviews (COI, Radiation/Biosafety)

NON-COMPLIANCE & REMEDIATION STRATEGIES

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Compliance Considerations

Your institution is liable for the conduct of the research. Period.

- It doesn't matter what IRB model you have, the liability for study conduct falls on the institution
- Institutions need policies and procedures for identifying and handling non-compliance
- Training, mentoring, monitoring, and quality assurance programs are key

Non-Compliance

Common Errors	Common Causes	Common Corrective Actions
Failure to follow protocol	Not enough time, staffing	Add personnel; resources
Incomplete case histories	Insufficient oversight or monitoring	Feasibility; reduce # studies
Insufficient source documentation	Lack of expertise/knowledge	Training, mentoring
Consent documentation errors	Insufficient systems/controls	SOPs, templates, system controls; QA monitoring
Failure to obtain IRB approval	Bad apple?	Behavioral modification/rehab; restrict research privileges

Remediation Strategies

Best Practices in Corrective & Preventive Actions

- Root Cause Analysis
  - Identify contributing factors, define underlying causes to identify appropriate corrective actions to prevent recurrence
- Design and implement corrective and preventive action plan
  - Simple & measurable; beware the kitchen sink strategy!
  - Incorporate timelines for implementation
  - Evaluate effectiveness of corrective actions
  - Document!

Who's Involved?

Research/Corporate Compliance

- Institutional Compliance Unit

Reviewing IRB

- Remember: this could be outside of your institution

Local IRB

- Didn't review the protocol, but do they have a role?

Research Integrity Officer/IO

- Can restrict privileges – must be involved?

Case Study

A routine Quality Assurance review identifies errors in informed consent documentation…

Step 1: Root Cause Analysis – who is on the team to assess? Use the Five Why's
Step 2: Develop Corrective and Preventive Action Plan
Step 3: Who approves the CAPA? IRB? Compliance? IO? All?
Step 4: Who verifies and documents the CAPA was effective in remediation?

What if reviewing and local IRB involved? What if there are differing opinions?
Who determines if errors are serious/continuing non-compliance?
Who reports to federal agencies?