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Updating the Common Rule Governing Human Subjects Research Protections

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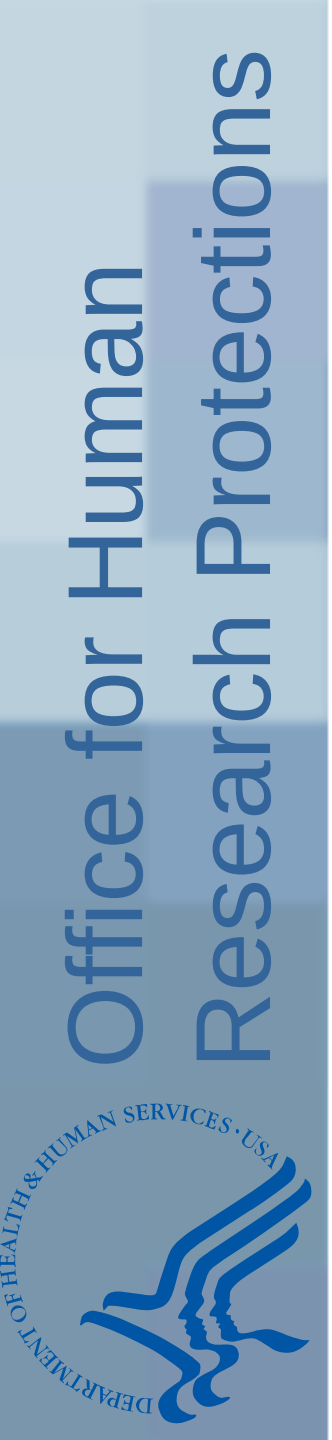
I. Background

- Twenty years have passed since the "Common Rule" was adopted
- Nature of research activities has changed dramatically.
- Multi-site studies; genomics; internet and information technology
- Time to update the Common Rule: goal of improving protections for subjects, while making the rules function more effectively
- Thus, an *Advance Notice of Proposed Rulemaking*



II. Ensuring Risk-Based Protections

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Goal is to better target time and effort spent on reviewing a study to the risk of the study.

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II. Ensuring Risk-Based Protections

Current framework has tiers of review:

- ***Review by a convened IRB*** — Studies with greater than minimal risk
- ***Expedited review*** –commonly single IRB reviewer
- ***Exempt*** --six categories exempted from IRB review altogether

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II. Ensuring Risk-Based Protections

- New standards for data security and information protection that would apply to appropriate studies
- IRB would no longer be responsible for reviewing this aspect of protocols

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II. Ensuring Risk-Based Protections

- ***Convened IRB Review*** — Only change: continuing review not required if only analyzing data or collecting new data from standard clinical follow-up

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II. Ensuring Risk-Based Protections

Eligibility for ***Expedited Review***:

- Regular updates to list of research activities that qualify for expedited review
- Presumption that a study which includes only activities on the list is a minimal risk study and should receive expedited review (reviewer option to send to convened IRB)
- Considering whether a study eligible for expedited review should be required to meet all of the current criteria for IRB approval

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Eliminating Continuing Review of ***Expedited*** Studies

- Default -- no continuing review for studies that qualify for expedited review
- Reviewer could make a specific determination (with justification) that continuing review is appropriate for a study

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II. Ensuring Risk-Based Protections

- Streamlining Documentation Requirements for ***Expedited*** Studies
- Templates for protocols and consent forms

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II. Ensuring Risk-Based Protections

Revising and expanding current ***exempt*** category:

- No longer fully "exempt"—adhere to data security rules, some consent rules
- Requiring brief registration form to be filed with institution
- Research could generally begin immediately after filing
- Eliminate current routine review of almost all exempt studies; audit some to verify qualification

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II. Ensuring Risk-Based Protections

Expansions of **"*exempt" categories***:

- Surveys conducted with competent adults would qualify
- Perhaps a new category for social and behavioral research involving specified types of benign interventions that are known to involve virtually no risk to subjects
- "Secondary" research with existing biospecimens and data would qualify, even if identifiers retained; consent rules

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III. Streamlining IRB Review of Multi-site Studies

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- Mandating that all domestic sites in a multi-site study rely upon a single IRB as their IRB of record for that study.

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IV. Improving Informed Consent

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Goal is to produce consent forms that do a much better job in informing prospective subjects by:

- Prescribing how information should be presented in consent forms
- Providing more specifics about content that should be in the forms, and about what should not be in them (vs. in appendix)
- Reducing institutional “boilerplate”

IV. Improving Informed Consent

- Written consent for biospecimens collected after effective date
- Open-ended standard consent form for giving consent to broad future use

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V. Strengthening Data Protections To Minimize Information Risks

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- As mentioned earlier: new data security protections that would apply to research involving identifiable information

V. Strengthening Data Protections to Minimize Information Risks

- Common Rule definition of when data is "identifiable" would be harmonized with definition in HIPAA Privacy Rule

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VI. Data Collection To Enhance System Oversight

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- Create a web-based portal for investigators to submit safety data and automatically have it delivered to appropriate agencies
- Harmonize safety reporting guidance across all Federal agencies
- Central repository

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VII. Extension of Federal Regulations

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- Require domestic institutions that receive some Federal funding from a Common Rule agency for research with human subjects to extend the Common Rule protections to all research studies conducted at their institution.

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VIII. Clarifying and Harmonizing Regulatory Requirements and Agency Guidance

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Request for Comments

How do differences in guidance from different agencies either strengthen or weaken protections for human subjects or the ability to conduct research?

- Should these differences be reduced?

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How to find the Advance Notice of Proposed Rulemaking:

www.hhs.gov/ohrp

Click the big blue button!