Office for Human Research Protections

Updating the Common Rule Governing Human Subjects Research Protections

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Disclaimer

The views expressed in this presentation and those of the presenter and do not necessarily represent the views of the Department of Health and Human Services or any subdivision thereof.
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.
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
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
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
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
II. Ensuring Risk-Based Protections

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
II. Ensuring Risk-Based Protections

• Streamlining Documentation Requirements for *Expedited* Studies

• Templates for protocols and consent forms
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
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
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.
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
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
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
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.
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?
How to find the Advance Notice of Proposed Rulemaking:

www.hhs.gov/ohrp

Click the big blue button!