Revisions to the Common Rule

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Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

Common Rule Revisions

- Revisions to Common Rule – the primary set of federal regulations for protecting research subjects – were published in Federal Register on January 19, 2017

Common Rule Revisions

- Information about the changes can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

Goals

- Strengthen protections, where appropriate
- Eliminate inappropriate administrative burdens

Effective Date

- The new rules become effective one year after publication
- Compliance with changes relating to multi-institutional (cooperative) research not required until three years after publication

Effective Date

- For studies approved by IRB prior to effective date, option to choose to apply new rules, else prior rules apply

Proposals not adopted

Many proposals *not* adopted:

- Covering de-identified biospecimens
- Changes dependent on standards not yet promulgated (e.g., privacy rules)
- Coverage of clinical trials that are not federally funded

Some of the major changes

- Improving informed consent (content and organization of consent forms)
- Single IRB for reviewing many studies, but great flexibility in expanded exception: where sponsor determines not appropriate for “particular context”

Some of the major changes

- Carve-outs from definition of research, and new or expanded exemptions
- New option of broad consent – very different from prior proposal (where often not optional)
- Elimination of continuing review requirement for many studies