Revising the Common Rule

What's in the Final Rule? What Happens Next?

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Agenda

• Where we are in the rulemaking process
• What’s in the Common Rule now
• How the rule has changed since the proposed rule
• Next steps for the Common Rule, for you, and for AAMC
  • When should you start implementing the requirements and new provisions?
Key changes to the current Common Rule

• New definitions: clinical trial, identifiable biospecimen, federal department or agency, written or in writing (to include electronic formats) (§__.102)

• Resolving some questions of applicability through activities “deemed not to be research” (§__.102(l))

• Requiring a single IRB for multi-site studies (§__.114)

• Modifying informed consent requirements
  • Changing the organization and content of information presented through informed consent (§__.116(a))
  • Creating “broad consent” as an alternative to study-specific informed consent, waiver, or deidentification (§__.116(d))
  • Allowing screening, recruiting, or determining eligibility without informed consent (§__.116(g))
  • Requiring posting of an approved consent form for each clinical trial (§__.116(h))
Key changes to the current Common Rule

- Shifting attention and restrictions to higher-risk studies
- More exemptions, some of which require “limited IRB review” of privacy protections ((§__.104(d))
- Elimination of continuing review for studies that undergo expedited review and those where interventions have concluded ((§__.109(f))
- Attempt to reduce duplicate regulation through exemption for secondary research using information regulated under HIPAA (§__.104(d)(4)(iii))
- Changes to the assurance process (§__.103)
- Requiring consultation across agencies regarding guidance, suggesting greater commitment to harmonization (§__.101(j))
Notable changes in the language of the Common Rule

• Vulnerability has been narrowed and reframed
• Tribal law has been incorporated throughout
• Exemptions have been moved and now have summary headings
• Biospecimens are explicitly incorporated
Treatment of biospecimens

Current Common Rule
• No mention of biospecimens
• Research with nonidentified biospecimens is not research with human subjects subject to the Common Rule

Proposed Rule
• Changed the definition of “human subject” to include a biospecimen, with sweeping implications for informed consent and tracking
• Proposed “broad consent” for all secondary research with biospecimens

Final Rule
• Limits scope to identifiable biospecimens
• Current rules about research with nonidentified biospecimens are generally unchanged
• Provides mechanism for reexamining what “identifiable biospecimen” means
• Adds exemptions for storage of and research with biospecimens for which broad consent was obtained
After the proposed rule, what changed in response to public comments?

- Scope of the regulation (not expanded as proposed)
- Treatment of biospecimens (substantially modified)
- Requirement to use not yet developed tools and templates (removed)
- Activities “excluded” from the regulations (removed)
  - QA/QI activities
- Standardized privacy safeguards (removed)
- Single IRB application (language changed to increase potential agency flexibility)
Unanswered questions and opportunities for clarification remain

• Innovations in informed consent
• Harmonization with FDA regulations
• Implementation of exemptions
• Flexibility in agency implementation of single IRB requirement
• Appropriate of common uses of broad consent
• QA/QI and standard of care research
Next Steps for the Common Rule

• Key Dates
  ▪ Publication Date: January 19, 2017
  ▪ Effective Date: January 19, 2018
  ▪ Compliance Date (for all but single IRB): January 19, 2018 (January 20, 2020 for single IRB)

• What could affect its implementation?
  ▪ Congressional action
    – E.g. Congressional Review Act, Midnight Rules Relief Act, REINS Act
  ▪ New administration approaches and priorities
    – Statements about significantly reducing regulations

• What should you be doing now?
  ▪ Prepare but don’t implement yet
Next Steps for the AAMC

• Upcoming:
  • COF Research Call Mid-February (ewilkerson@aamc.org)
  • GRAND Spring Meeting April 18-20 (itartakovskyy@aamc.org)
  • Steering committee discussions and group updates on request
  • Additional calls, detailed implementation-focused webinars and resources (www.aamc.org/commonrule)

• What further resources or discussions would be helpful to you as you prepare to implement the new rule?

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