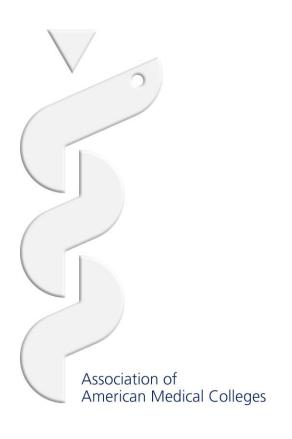


Revising the Common Rule

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?



Advance Notice of Proposed Rulemaking (ANPRM) July 26, 2011



Public Comment Period July – October 2011

Notice of Proposed Rulemaking (NPRM) Sept 8, 2015



Public Comment Period September 2015 – January 2016

Final Rule January 19, 2017



Implementation Preparation

Compliance Date
January 19, 2018/January 20, 2020**



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 studyspecific 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
 - January 20, 2017 Memo: "Regulatory Freeze Pending Review"
 - 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 (itartakovsky@aamc.org)
 - Steering committee discussions and group updates on request
 - Additional calls, detailed implementationfocused 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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