AAMC
Tomorrow's Doctors, Tomorrow's Cures

Learn
Serve
Lead

Revising the Common Rule

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

Heather Pierce, JD, MPH
Senior Director, Science Policy
Regulatory Counsel
hpierce@aamc.org
January 25, 2017

Association of
American Medical Colleges

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?

AAMC

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**

AAMC

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))

AAMC

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

AAMC

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)

AAMC

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

AAMC

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 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?

  Heather Pierce: hpierce@aamc.org

AAMC

AAMC

Tomorrow's Doctors, Tomorrow's Cures

Learn

Serve

Lead

Association of
American Medical Colleges