AAMC
Tomorrow's Doctors, Tomorrow's Cures

Learn
Serve
Lead

The Revised Common Rule

Where Are We Now?
What Happens Next?

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

June 20, 2018

Association of
American Medical Colleges

Agenda

- Status of the Revised Common Rule
- Overview of Key Changes
- Next Steps for Implementation
- Discussion

AAMC

Where We Were at the End of the Last Administration

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

Effective and Compliance Dates
January 19, 2018
(Single IRB January 20, 2020)

AAMC

What's happened since January 2017?

Or: The Long and Winding Rulemaking Road

AAMC

What Happened Since January 2017?

May 2017: Federal officials assert that the Common Rule is in a "holding pattern" and that the administration is considering a delay.*

June 21, 2017: AAMC, AAU, APLU, COGR submit a letter to OHRP requesting one year delay in compliance date*

October 7, 2017: Proposed Rule Submitted to Office of Management and Budget (OMB) for Review, "*Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year*"

December 12, 2017: AAMC Meets with OIRA at OMB*

December 20, 2017: Deadline for NPRM with 30 day comment period elapses

January 4, 2018: Final Rule Submitted to OMB for Review: "*Delay of the Revisions to the Federal Policy for the Protection of Human Subjects*"

January 22, 2018: Interim Final Rule (released January 17, 2018) Delayed effective and compliance date for six months (*July 19, 2018)*

*** Resources available at www.aamc.org/commonrule**

AAMC

Notice of Proposed Rulemaking

Published April 20, 2018

- **Proposed change to compliance date from July 19, 2018 to January 21, 2019 (additional six months)**
  - Single IRB compliance dates remain January 20, 2020

- **Regulated entities must comply with all current Common Rule (pre-2018 Common Rule) requirements until January 21, 2019**

- **Voluntary adoption of three "burden reducing" provisions for particular studies during delay period**
  1. Use of the revised definition of "research"
  2. Allowance for no annual continuing review for certain categories of research
  3. Elimination of requirement for IRB review of grant applications or other funding proposals related to research

AAMC, AAU, APLU, and COGR submitted a letter to HHS supporting delay and voluntary adoption of burden-reducing provisions.

AAMC

BREAKING NEWS

Final Rule: " Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period"

Published in Federal Register June 19, 2018

Bottom Line: Institutions must be in compliance with most provisions of the Common Rule on January 21, 2019

AAMC

Key changes in the Final Rule

AAMC

Major Changes

- Scope
- Definitions
- NOT Research
- Expanded Exempt categories
- Limitation of Continuing Review
- Informed Consent
  - New elements
  - Waiver and alteration
  - Broad consent
- Cooperative Research

AAMC

Scope

- Still limited to federally conducted or supported research
- Mechanism of extending beyond federal categories to change
  - No longer using the Federalwide Assurance mechanism
  - No longer a “check the box” option*
- Now covers independent IRBs, not just institutions

* But stay tuned for updates (as per June 19, 2019 Final Rule)

AAMC

Definitions: Human Subject _.102(e)(1)

"Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains *information or biospecimens* through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or *identifiable* biospecimens."

"Information or biospecimens" replaces "data"

Role of identifiability is clarified

Definitions: Intervention _.102(e)(2) and Interaction _.102(e)(3)

- Intervention includes “physical procedures by which *information or biospecimens* are gathered (*e.g.*, venipuncture)”
  - Again, “information or biospecimens” replaces “data”
- Interaction includes communication or interpersonal contact

AAMC

Definitions: Private Information

The definitions are essentially unchanged

(4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

If it isn't identifiable, it doesn't involve a human subject, and it isn't under the Common Rule

AAMC

Definitions: Identifiable Biospecimen _.102(e)(6)

"An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen."

If it isn't identifiable, it doesn't involve a human subject, and it isn't under the Common Rule

Identifiable *still* means that the "identity of the subject is or may readily be ascertained by the investigator" or associated with the information or biospecimen

New requirements to reexamine the meanings of "identifiable private information" and "identifiable biospecimen" and technologies and techniques that could generate them

- Within one year and at least every four years
- Published list of technologies and techniques

AAMC

Revised Common Rule Requires Distinguishing Between Five Categories of Activities

1. Activity that doesn't meet the definition of research with human subjects
2. Activity that may meet the definition but deemed not to be research ("NOT Research")*
3. Research that is truly exempt from the regulation
4. Research that is exempt but with conditions*
5. Non-exempt research with human subjects

AAMC

NOT Research

As part of definition of research – what is "NOT Research"

- Scholarly and journalistic activities
- Public health surveillance
- Criminal justice activities
- Authorized operations in support of national security

Purpose

- To "resolve long-standing debate and uncertainty"

AAMC

Expanded Exempt Categories

Now 8 categories (from existing 6)

- Deleted one, modified several and added 4, including 3 new exemptions related to secondary use of data or biospecimens
- “Limited IRB Review” is required for some

Major change:

- Ability to use and record identifiable data and biospecimens if certain conditions met (not allowed in existing Common Rule)

AAMC

Exempt Categories __.104(d)

1. Educational research
2. Interactions: educational tests, surveys, observation of public behavior (Revised)*
3. Benign behavioral interventions (New) *
4. Secondary research for which consent is not required (New – includes HIPAA exemption)
5. Federal research and demstration projects
6. Taste and food quality
7. Storage or maintenance for which broad consent is required (New) *
8. Secondary research for which broad consent is required (New) *

*** Some form of Limited IRB Review is required**

AAMC

NEW - Exemption __.104(d)(3)

Benign behavioral interventions with collection of information (verbal, written, audiovisual recording) from **adult** subject who prospectively agrees and one of the following is met:

(A) Recorded information cannot readily identify the subject (directly or indirectly/linked)

(B) Any disclosure of responses outside of the research would not reasonably place subject at risk (criminal, civil liability, financial, employability, reputation)

(C) Recorded information is identifiable (directly or via link) and IRB conducts a limited review to make __.111(a)(7) determination

SACHRP has taken up this issue and developed recommendations

AAMC

Caution: Different limited IRB reviews for different exemptions

For exemptions 2 and 3 limited IRB review is for __.111(a)(7) determination

- "When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects"

For exemptions 7 and 8 limited IRB review for __.111(a)(8)

- Mainly relating to Broad consent

Guidance has been requested

AAMC

Limitation of Continuing Review

Continuing review NOT required for research that has:

- Been reviewed by expedited process
- Progressed to data analysis or collection of routine care data

Purpose:

- Removing burden of seemingly un-necessary review

Warning: institutional responsibility for all research activities

- Investigators remain responsible for all required reporting (e.g., AEs, changes)
- CR served as good reminder/check-in for investigators – without it, will compliance fall?
- Institutions may consider a non-regulatory tracking/checking-in requirement

AAMC

Informed Consent – Key changes

- New organization and concise summary of information presented informed consent (__.116(a))
- “Broad consent” as an alternative to study-specific informed consent, waiver, or deidentification (__.116(d))
- Waiver and alterations (__.116(e) and (f))
- Screening, recruiting, or determining eligibility without informed consent (__.116(g))
- Posting of consent forms (__.116(h))

AAMC

Informed Consent – Key considerations

Changes are limited to form, not process of informed consent

Formatting changes and additional elements to be included when appropriate

- Existing eight required elements unchanged
- Additional elements added

Waiver of informed consent

- New additional finding for the IRB when identifiable private information or biospecimens: the research could not be practicably carried out if not identifiable
- Considerations for IRBs: What is the process for incorporating this new element into the waiver request?
- If subject refused broad consent, no waiver for storage/maintenance/research use [tracking difficulties]

Required posting of ICFs for clinical trials

- At the end of the study
- Only one consent form required

AAMC

Broad Consent

Included in the rule as an alternative to traditional study-specific informed consent

Never required (but certain exemptions are based on its prior use)

Used only for storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens

Alternatives:

- Informed consent under __.116(a)
- De-identification
- Waiver of informed consent (unless previously asked for broad consent and subject refused)

When might you use broad consent? Will you?

Does broad consent increase autonomy?

Broad consent might not dictate whether specific research can take place

Cooperative Research (Single IRB)

For all multi-site research involving domestic sites

Does not go into effect until 2020 (unless research is NIH funded – see NIH policy)

Purpose:

- Streamlining and harmonization

Institutional responsibility remains for all research activities

- Logistics of relying on an external IRB or being the reviewing IRB
- Completion of all institutional requirements
  - Ancillary reviews
  - Conduct of the research

AAMC

Implementation Steps and Challenges

AAMC

Next Steps
What does this mean for implementation?

- **Until July 19, 2018, institutions must comply with the current Common Rule ("Pre-2018 requirements")**
  - Includes: Research initially approved by an IRB, research waived under §101(i), or studies determined as exempt *before* July 19, 2018
- **Research initiated *on or after* January 21, 2019 must comply with the 2018 requirements** (unless further action to delay the compliance date is taken)
  - After the effective date, institutions may choose whether research approved *before* January 19, 2019 will remain under the pre-2018 requirements or comply with the 2018 requirements
- **Research initiated or ongoing *between* July 19, 2018 and January 21, 2019 must comply with the 2018 requirements, *unless* the institutions would like to adopt one or more of the "three burden-reducing provisions"**

AAMC

Implementing the Burden-Reducing Provisions

- Voluntary adoption of three "burden reducing" provisions for particular studies during delay period
  1. Use of the revised definition of "research"
  2. Allowance for no annual continuing review for certain categories of research
  3. Elimination of requirement for IRB review of grant applications or other funding proposals related to research

- **NOTE**: Adopting any provision during the delay period "transitions" the study to the new Common Rule – must be in full compliance January 21, 2019
  - Remaining under current CR in delay period "grandfathers" study for its entirety

AAMC

Next Steps:
When can we begin implementing the revised rule?

- *Generally, before January 21, 2019*, institutions may only implement certain provisions of the new requirements that do not conflict with the pre-2018 requirements

- Examples:
  - **Requirement *not in* conflict:** Additional elements of informed consent (§.116(b)(9), (c)(7)-(9)) may be incorporated in consent forms
  - **Requirement *in conflict:*** Use of new exemption category (d)(3), benign behavioral interventions could not be used before compliance date

AAMC

“But what about the guidance?”

- OHRP Decision Charts
- Inclusion of key information in informed consent documents
- Posting of informed consent forms on a public website
- Limited IRB Review
- “Reasonable person” requirement
- Identifiability
- Benign behavioral interventions
- Training resources
- Broad consent

SACHRP July 10-11, 2018 meeting will discuss subcommittee recommendations on “key information” required at the beginning of consent forms

AAMC

Next Steps for the AAMC

- Institutional survey on implementation suggestions http://aamc.org/commonrulesurvey
- Opportunities for institutional coordination (sharing implementation strategies, creation of implementation check-list)
- Following FDA harmonization efforts with Common Rule

AAMC

Stay Updated

Online resources and HHS updates on AAMC's Common Rule webpage: www.aamc.org/commonrule

- Updates on HHS guidance documents and other agency resources when available
- Posting of institutional tools and resources
- **http://aamc.org/commonrulesurvey**

Contact us:

- Heather Pierce
  - hpierce@aamc.org
  - @HeatherHPierce -Twitter
- Daria Grayer (dgrayer@aamc.org)

AAMC

Questions and Discussion

AAMC

AAMC

Tomorrow's Doctors, Tomorrow's Cures

Learn

Serve

Lead

Association of
American Medical Colleges