The Revised Common Rule

What’s in the Interim Final Rule? What Happens Next?

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

January 23, 2018
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)
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*

**August 2, 2017**: SACHRP submits letter to HHS Secretary Price*


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

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


**Interim Final Rule** Announced January 17, 2018
Published January 22, 2018*

Effective and compliance date delayed until July 19, 2018
Compliance date for Cooperative research (single IRB) unchanged

* Resources available at www.aamc.org/commonrule
Purpose of Delay

Provides additional time for implementation and compliance with the revised Common Rule (“2018 Requirements”)

- Allows institutions time to update polices, processes, and electronic systems
- Gives Common Rule departments and agencies time to prepare and issue guidance materials

Allows Common Rule departments and agencies to seek public input on an NPRM to further delay the 2018 requirements (until January 21, 2019)

- Note that the proposed rule from October 7th is still “under review” by OIRA
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 July 19, 2018 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 July 19, 2018 will remain under the pre-2018 requirements or comply with the 2018 requirements
    - See transition provisions, ___101(l)
- Note that the NIH Policy on cooperative research (single IRB) is unaffected by this delay – effective January 25, 2018

5

AAMC
Important: The revised regulations are not in effect yet

- Before July 19, 2018, institutions may only implement certain provisions of the 2018 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:** Elimination of continuing review of research in certain circumstances (§.109 (f)) would violate the current Common Rule and may not be implemented yet.
Opportunities for Public Feedback

- **Interim Final Rule**
  - Comments due **March 19, 2018** [docket ID: HHS-OPHS-2017-0001]
  - Should I comment on the IFR? That depends…

- **Notice of Proposed Rulemaking (in development)**
  - Common Rule departments and agencies developing NPRM to further delay compliance date
  - Proposed final rule under review at OMB (received October 7, 2017)

- **FDA Harmonization Efforts** [required by 21st Century Cures Act]
  - Effort to align the revised Common Rule through a public rulemaking process has not started
  - Opportunity to comment on FDA’s review of existing regulations and requirements per Executive Orders (13771 and 13777) on reducing regulatory burden
    - Comments due **February 5, 2018** [docket ID: FDA-2017-N-5093]
Next Steps for the AAMC

• **Additional calls focused on implementation**
  • Post-call survey
  • Visit [www.aamc.org/commonrule](http://www.aamc.org/commonrule) for future registration information – and recording of today’s call
  • Opportunities for institutional coordination

• **Online resources and HHS updates on AAMC’s Common Rule webpage:** [www.aamc.org/commonrule](http://www.aamc.org/commonrule)
  • Updates on HHS guidance documents and other Agency resources when available
  • Posting of institutional tools and resources

• **Contact us:**
  • Heather Pierce hpierce@aamc.org, @HeatherHPierce on Twitter
  • Daria Grayer dgrayer@aamc.org