

UPDATE ON REVISIONS TO THE COMMON RULE

Laura Odwazny
Office of the General Counsel, HHS



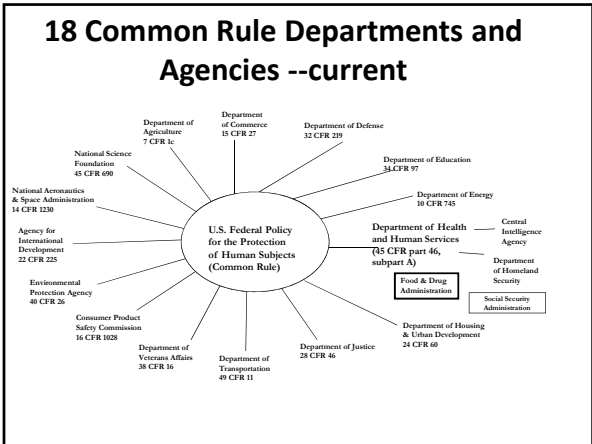
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- This presentation does not constitute legal advice.
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The “Common Rule”

- U.S. Federal Policy for the Protection of Human Subjects (1991)
- Three basic protections for human subjects:
 - Institutional Assurances
 - Each institution engaged in human subject research governed by the Common Rule must provide an assurance to Federal Dept/Agency that it will comply with the regulations
 - Institutional Review Board (IRB) Review
 - Approval necessary prior to beginning human subjects research
 - Informed Consent
 - Prior to involvement of human subjects in research
 - May be waived in certain circumstances



The revised Common Rule

- Published January 19, 2017
- Not yet effective
- **NOTE:** Current rule applies until revised rule becomes effective
- Only provisions that do not conflict with the current rule may be implemented now

Major changes

- Informed consent
 - Revised content, format, and new posting requirement
 - Allowance for “broad consent” for unspecified secondary research use
- Mandatory single IRB review
 - Common Rule requirement effective in 2020, NIH policy issued first
- Elimination of continuing review for much low risk research
- New/revised exemptions eliminate required review of much social and behavioral research

The revised Common Rule



- Published January 19, 2017
- **Not yet effective**
- **NOTE:** Current rule

UPDATED
Interim Final Rule
Displayed 1/17/18

Interim Final Rule (displayed 1/17/18, published 1/22/18)

- Legal impact:
 - Delayed the effective date of the revised Common Rule until **July 19, 2018, and**
 - Amended the transition provision of the not-yet-effective revised Common Rule to make general compliance date **July 19, 2018.**

Includes statement that the revised Common Rule could be further delayed through other rulemaking.

Under revised Common Rule and IFR...

- Revised Common Rule provisions that conflict with current Common Rule can't be implemented in lieu of current Rule until July 19, 2018 (the effective and compliance date of revised Rule)
- After July 19, 2018, ongoing research initiated before that date may:
 - Continue to follow current Common Rule
 - Allowable for lifetime of the study, unless institution chooses to transition research to the revised Rule at some point
 - OR**
 - If decision to transition the study to revised Common Rule is made and documented, follow revised Rule as of date of transition
- Research initiated on or after July 19, 2018 must follow the revised Common Rule

BREAKING NEWS: Another Common Rule delay proposal!



• Published April 20, 2018



NPRM published 4/20/18: The proposal

- 6 months further delay in general compliance date – until **January 21, 2019**
- Between July 19, 2018 - January 21, 2019, ongoing research can:
 - Follow current Common Rule
 - Allowable for lifetime of the study, unless institution chooses to transition research to the revised Rule at some point
 - OR**
 - Take advantage of an additional flexibility: Follow current Common Rule + 3 burden-reducing provisions from revised Rule (substituted for comparable current Rule provisions) if decision to transition the research to revised Common Rule is made and documented
 - Then, as of January 21, 2019, the research must follow entire revised Rule

Proposal: general compliance date delayed

- Revised Common Rule still would keep effective date of July 19, 2018, only general compliance date would be delayed
- As proposed, **the entire revised Rule could not be implemented until the general compliance date of January 21, 2019**, even if institution is ready
 - Aspects of revised Rule that do not conflict with current Rule can be implemented at any time (as is currently the case)
 - Some provisions do conflict with current Rule (e.g., new exemptions) and could not be implemented until general compliance date

Proposal: 3 burden reducing provisions

- Revised definition of “research”
 - Carves out certain scholarly and journalistic activities, public health surveillance activities, collections/analyses for criminal justice or criminal investigative purposes, authorized operational activities in support of specified intelligence/defense/security missions
- Eliminates IRB review of grant applications or other funding proposals
- Allows no continuing review for certain low-risk research, unless otherwise required by the IRB
 - Research eligible for expedited review (under current Rule and list)
 - Research that involves only data analysis, or accessing follow-up clinical data from clinical care procedures

Proposal: transition decision during the delay period

- Transition decision can be for:
 - individual studies
 - a class of studies (e.g., all studies eligible for expedited review)
 - institution’s entire research portfolio
- Proposal would allow institution or IRB to document institution’s transition decision, instead of just IRB (as per the 2017 final rule)
- Date of documentation of transition decision = compliance date for 3 burden-reducing provisions, which then are considered in enforcement by supporting Federal agency

Comment sought on alternatives to primary NPRM proposal

- Alternatives specified in the preamble
- Revised Rule goes into effect as scheduled on July 19, 2018, and full compliance required as of that date
 - Delay of both effective and general compliance date until January 21, 2019, with no option to use 3 burden-reducing provisions during delay year
 - Delay of both effective and general compliance date beyond January 21, 2019

Implementation Decisions for Research Institutions

If NPRM proposal is finalized:

- To transition or not to transition ongoing research to revised Rule during delay period? Or keep under prior rule?
 - Consider both new flexibilities (e.g. elimination of continuing review) vs. potential application of new requirements (e.g. posting of informed consent)
 - Consider stage of the research – e.g. will transitioned study be open to enrollment, such that after compliance date consent form would need to be revised to comply with new revised Rule requirements?

Harmonization Considerations: FDA

Preamble to revised Common Rule:

“...to the extent appropriate, the intent is to ...consider the need for updates to FDA regulations and other relevant federal departmental or agency regulations with overlapping scope.”

21st Century Cures Act: Protection of human research subjects
 “(a) In general.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, **the Secretary of Health and Human Services...shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations...**
 ...

(d) Timing.—The Secretary shall complete the harmonization described in subsection (a) not later than **3 years after the date of enactment** of this Act.” (12/13/16)

Remaining Implementation Questions...

- When will the changes made by the revised Common Rule go into effect and be enforceable?
 - July 19, 2018, as per the interim final rule, or
 - Further delay, as proposed in the NPRM?
- When will research institutions implement the revised Common Rule changes in their forms, templates, SOPs?
 - Now: possible to implement any new provisions that do not conflict with the current Common Rule
 - Later: any new provisions that conflict with the current Common Rule
- Will FDA harmonize? And if so, when?



Quick tip: Rulemaking 101 overview

- “Notice and comment” rulemaking/ Informal rulemaking
 - NPRM, public comment period, final rule published 30 days before effective date
 - Example: Revised Common Rule NPRM → final rule rulemaking process
- Interim final rule
 - Rule meets “good cause” exception from prior notice and comment (so no NPRM)
 - Good cause= n+c “impracticable, unnecessary, or contrary to the public interest”
 - Example: IFR delaying Common Rule final rule, displayed 1/17/18
- Direct final rule
 - Final rule published with statement that, unless an adverse comment received, rule becomes effective on specified date (later than 30 days after comment period)
 - If a single adverse comment received, final rule withdrawn and agency proceeds with notice and comment rulemaking
 - Generally used for noncontroversial rules

**Spring 2018 Unified Agenda (May 8, 2018):
FDA entries**

- Direct final rule: Amend FDA IRB and informed consent regulations to harmonize with revised Common Rule (12/18)
 - New definitions, conforming wording, minor editorial changes
- Direct final rule: Codify waiver of informed consent for minimal risk clinical investigations, harmonized with the Common Rule waiver provision (5/18)
- Notice of proposed rulemaking: Proposal to require sIRB review of multisite research conducted in the U.S., with exceptions, and establishes IRB recordkeeping requirements when reviewing IRB is not the institutional IRB (12/18)

**THANKS FOR YOUR
ATTENTION!**

QUESTIONS?
