UPDATE ON REVISIONS TO THE COMMON RULE

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Disclaimer – Laura Odwazny

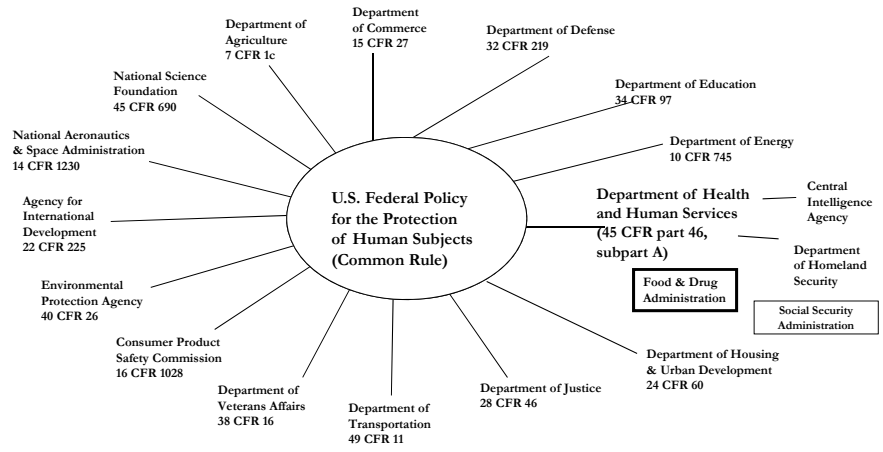
- This presentation does not constitute legal advice.
- The views expressed are the presenter's own and do not bind the U.S. Department of Health and Human Services or its operational components.

2

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

18 Common Rule Departments and Agencies --current



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 applies until revised

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**.

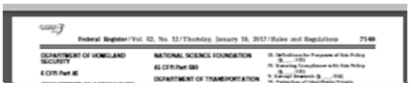
Includes statement that the revised Common Rule could be further delayed through other rulemaking.

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?