Key Changes in the Common Rule

Winona State University
Institutional Review Board (IRB)
Updates to the Common Rule

- In 2017, sixteen federal agencies published the first revisions to the Common Rule governing protection of human subjects participating in research since 2005.

- Intent was to modernize, strengthen, and make more effective the current system of oversight.

- Revisions to go into effect on July 19, 2018 (maybe).
Key revisions

• Expedited – continuing review
• Exempt categories – expansions, additions
• Informed consent – organization, detail, language
• Cooperative research – single oversight
Expedited review amendments

- Continuing review eliminated for minimal risk studies

- IRB may mandate continuing review if it would enhance protection of human subjects

- PIs remain obligated to report various developments (unanticipated problems, study changes, etc.)
Exempt review amendments

- Expansion or revision in five of the six existing categories
- Two new categories
Exempt review amendments (2)

1. Research involving educational methods, if the research is not likely to adversely affect instruction time or student performance *(restrictions added)*

2. Educational testing if any recorded information is de-identified, if disclosures of information would not place subjects at risk, or if the recorded information has not been de-identified and the procedures have been reviewed by an IRB *(expanded)*
3. Research involving benign behavioral interventions with adults when information is limited to verbal or written responses or AV recordings, if any recorded information is de-identified, if disclosures of information would not place subjects at risk, or if the recorded information has not been de-identified and the procedures have been reviewed by an IRB (new)
4. Secondary research use of identifiable private information if one of the following is met: (i) information is publicly available; (ii) it is recorded so that the identity of subjects cannot readily be ascertained directly or through identifiers and subjects will not be re-identified; (iii) it involves only information collection and analysis involving use of identifiable health information when that use is regulated for “health care operations” or “research;” or (iv) research is conducted by or on behalf of a federal department or agency using government-generated or collected information obtained for non-research activities, and the information is protected by federal privacy standards (new, expanded)
Exempt review amendments (5)

5. Research and demonstration programs designed to study, evaluate, improve public benefit or service programs, including federally supported research identified on a published list prior to the study (expanded)

6. Taste and food quality evaluation, consumer acceptance studies (no changes)
Exempt review amendments (6)

7. Storage or maintenance of secondary research for which broad consent is required *(new)*

8. Secondary research for which broad consent is required. Research using identifiable private information or biospecimens for secondary research use, if (i) broad consent was obtained for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens; (ii) documentation was obtained of informed consent or waiver of documentation of consent; (iii) an IRB conducts a limited review. *(new)*
“Not research”

- Scholarly and journalistic activities, such as oral history, journalism, biography, literary criticism, legal research, historical scholarship

- Public health surveillance activities conducted, supported, required, requested, authorized by a public health authority
Informed consent revisions

• “Information presented in sufficient detail and organized and presented in a way that does more than provide a list of isolated facts …”

• Explain to prospective subject or LAR why one might or might not want to participate in clear, concise, understandable language
Consent form requirements

• Consent is being sought for research and participation is voluntary
• Research purpose, expected duration of participation, procedures
• Reasonably foreseeable risks or discomforts
• Expected benefits to participants or to others
• Alternative procedures or treatments (if any) that might be advantageous to participants
Broad consent for biospecimens or individually identifiable data

• Researchers may now seek broad consent, which covers current and future unspecified research using the same biospecimens or data

• Consent must explain types of research that may be conducted, if identifiable information will be shared or stored, if subject will share in any commercial profit, if research will include whole genome sequencing, if results will or will not be disclosed to subject

• Subjects may choose to consent to parts of the research
Cooperative research revisions

- All U.S. institutions engaged in cooperative research must rely on a single IRB as reviewing IRB for the study

- Compliance date for this revision extended to January 20, 2020