# Common Rule Summary Table

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| **Effective Date** | January 19, 2018. The effective date for cooperative research is January 20, 2020 |
| **Biospecimens and Private Information** | The final rule does not expand the definition of "human subject" to include non-identified biospecimens but does alter the definition which now includes identifiable biospecimens. Identifiable Biospecimens and identifiable private information are treated equally in the final rule and these definitions will be re-examined within one year of publication and every four years thereafter. "If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance." A similar process will be followed to "assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information," or "identifiable biospecimens." The final rule does not adopt the proposal for more stringent waiver criteria that would have made waiver for secondary research use of biospecimens "very rare." |
| **Informed Consent** | Per the final rule, "Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research." It does not include the NPRM proposal that certain information be included only in the appendices. Additional elements of informed consent have been added, including a requirement for language indicating that identifiers might be removed from identifiable private information or identifiable biospecimens and whether such information or biospecimens might or will not be used for future research studies. In addition, "where appropriate," information on whether biospecimens will be used for commercial profit; whether results will be disclosed to the subject; and whether the research might include whole genome sequencing. Any version of an IRB approved consent form for clinical trials conducted or supported by a Common Rule department or agency must be posted on a publicly available federal website after recruitment ends but not later than 60 days after the last study visit by any subject. The final rule allows for redaction with approval. |
| **Exclusions and Exemptions** | The final rule does not include the proposed concept of "excluded" activities. It modifies the definition of research, "what constitutes research," and now names activities not considered research such as certain scholarly and journalistic (including oral history), public health surveillance and criminal justice and intelligence activities. A proposed exclusion for QA/QI activities was dropped because it "might have inadvertently created inappropriate obstacles." The rule adds to and modifies existing exemptions. This includes modifying previous exemptions to allow use of identifiable information with limited IRB review; inclusion of benign behavioral interventions; and storage, maintenance and secondary use of identifiable private information and identifiable biospecimens where broad consent is obtained consistent with the final rule, including six additional consent elements. Secondary research using identifiable private information or identifiable biospecimens without consent is exempted if the research only involves collection and analysis of identifiable information regulated under HIPAA or non-research government information in compliance with applicable federal requirements. A decision tool was not included but may be developed at a future date. |
| **Continuing Review** | Continuing review is eliminated for all studies that undergo expedited review and research that has progressed to the point that it involves only data analysis or accessing follow-up clinical data as part of clinical care, unless the reviewer documents a rationale for conducting continuing review. The final rule does not require investigators to provide annual confirmation to the IRB that research is ongoing and that no changes have been made. |
| **Extending Coverage** | The final rule does not extend coverage to non-federally funded clinical trials. |
| **Cooperative Research** | The final rule mandates the use of a single IRB for multisite studies. Federal departments or agencies supporting or conducting the research can determine that the use of a single IRB is not appropriate for particular contexts. The final language allows the lead institution to propose the reviewing IRB, "subject to the acceptance of the federal department or agency supporting the research." The agreement for oversight between the institution and the organization operating the IRB must be documented and include the responsibilities of each. |
| **Privacy and Security Safeguards** | Per the preamble, "the final rule does not adopt the privacy and security provisions proposed …but rather retains and acknowledges the IRB's role in ensuring that privacy safeguards are appropriate…" The final rule includes a new provision that requires the Secretary of HHS to issue guidance to assist IRBs in assuring appropriate privacy and security safeguards. |
| **Other Changes** | HHS plans to eliminate the voluntary extension of the FWA. The final rule eliminates the requirement that grant applications undergo IRB review and approval. The Secretary's list of categories of research eligible for expedited review will be evaluated at least every 8 years. |