



Health Care ADVISORY ■

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HHS Subjects Human Research to an Updated Common Rule

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On January 19, 2017, the Department of Health and Human Services (HHS) [issued revised regulations](#) updating its Federal Policy for the Protection of Human Subjects, better known as the Common Rule. HHS called the Final Rule “an effort to modernize, simplify, and enhance the current system of oversight,” which had not been updated since 2005. The new regulations attempt to make more uniform the regulatory requirements of the 16 federal entities that currently oversee human subjects research and to which the Common Rule applies. However, how the Common Rule will be ultimately harmonized with U.S. Food and Drug Administration (FDA) human subjects regulations – a change required under the directives of the 21st Century Cures Act – remains an open question for implementation by the new Administration.

What stakeholders may find most notable are the numerous changes included in the Notice of Proposed Rulemaking that were not incorporated into the Final Rule after HHS’s review of more than 2,100 public comments. Most notably, the agency declined to expand the Rule to cover clinical trials that are not federally funded, as well as nonidentifiable biospecimens. Additionally, the Final Rule does not include the more stringent privacy safeguards for identifiable private information and identifiable biospecimens that HHS previously proposed.

The Final Rule becomes effective on January 19, 2018. The compliance date for all sections except § _____.114(b), which addresses cooperative research, is January 19, 2018; the compliance date for § _____.114(b) is January 20, 2020.

Who Must Comply with the Common Rule?

- The Rule applies to any human subjects research “conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research.” The Final Rule also applies to institutional review boards (IRBs) reviewing such research. Practically speaking, the Rule applies to most research supported by federal funds. In addition, any institution that has executed a Federalwide Assurance can voluntarily extend its commitment to apply the Common Rule to all human subjects research they conduct, regardless of the funding source.

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- Human subjects research has been redefined to include any activity that involves a “systematic investigation” of “living individual[s]” about whom the person conducting the research uses “information or biospecimens [obtained] through intervention or interaction with the individual” or “[o]btains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
- Under § ____.101(a), the Common Rule now applies to IRBs not operated by an institution holding a Federalwide Assurance. Departments and agencies adhering to the Common Rule will be able to enforce compliance directly against such IRBs instead of taking compliance actions against the institutions that relied on them.

Who Is Exempt?

Of the eight areas of human subjects research exempted from the Common Rule, exclusions of secondary research activities will be most important for stakeholders. Secondary research of “identifiable private information or identifiable biospecimens” can be exempt from the Final Rule either without consent or with “broad consent.” The research may be exempt without consent when the identifiable information/biospecimens:

- Are publically available.
- Do not allow for subjects’ identities to be readily ascertained, and the investigator will neither contact subjects nor attempt to re-identify the subjects.
- Are collected or analyzed for “health care operations,” “research,” or “public health activities and purposes,” as defined in 45 CFR Part 164.
- Are used in research conducted by or on behalf of a federal entity “using government . . . information obtained for nonresearch activities” if the information will be maintained in accordance with Section 208(b) of the E-Government Act of 2002, the Privacy Act of 1974, and, if applicable, the Paperwork Reduction Act of 1995 (e.g., secondary research conducted using identifiable biospecimens, so long as any identifiable private information is appropriately maintained and protected).

Key Changes to the Common Rule Most Likely to Affect Stakeholders

Expedited review

IRBs may opt for an expedited review when there are only minor changes to already-approved research or the activity is listed on the HHS Secretary’s list of minimal-risk activities. If an IRB determines that full review is required for an activity that the Secretary has deemed minimal risk, the IRB needs to document its justification.

Vulnerable populations

Of the criteria for IRB approval established by the Final Rule, the most notable changes are related to vulnerable populations and ensuring privacy protections. When a study is likely to include subjects from vulnerable populations (e.g., “children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons”), the IRB must determine that appropriate measures are in place to protect these subjects’ rights. The IRB must also determine that the research includes measures to preserve data privacy and confidentiality; however, the Final Rule requires the HHS Secretary to issue guidance on what these measures should be.

Single IRB requirement

For research projects conducted in the U.S. involving multiple institutions (i.e., “cooperative research”), individual institutions may no longer operate their research activities based on the review of their local IRB. Instead, one IRB review must be conducted for the entire research project, and each institution involved in that cooperative research must adhere to that review. This provision does not apply if a single IRB review is prohibited by law or found to be inappropriate by the federal entity supporting the research.

Expanded definition of informed consent

The Rule subdivides informed consent into three categories: general elements, basic elements, and additional elements. The general elements include a new requirement that the consent form start with “a concise and focused presentation of the key information” likely to help someone understand the pros and cons of study participation. HHS provides that this section should cover the following topics: (1) the voluntary nature of participation; (2) the person is being asked to participate in research; (3) the research’s purpose; (4) the time commitment for subjects; (5) procedures included in the research; (6) risks (e.g., “the most important risks, similar to the information that a doctor might deliver in the clinical context”); (7) benefits of the research; and (8) treatment options other than participating in the research. As an indication of what would not meet this requirement, the notice for the Final Rule gives the example of “a 10-page description of elements such as potential risks, accompanied by lengthy and complex charts and graphs.”

The basic elements of informed consent include discussing in more detail the topics in the new introductory section, confidentiality, whether any compensation or medical treatments might be made available in the case of injury from participating, how to get study-related questions answered, and whether and how a subject’s information or biospecimens may be handled as part of other research.

The additional elements are meant to be discussed when applicable and now include whether a subject’s biospecimens would be used for profit and the subject’s portion of that profit (if any), whether research results would be disclosed to subjects, and whether research may include “whole genome sequencing.”

New category of broad consent

Broad consent, as compared to the full informed consent, is only allowed “for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.” This would apply when the information or biospecimens were collected for another research study or nonresearch purposes. While certainly briefer than the full requirements of informed consent, it still includes five of the nine basic elements and two of the nine additional elements, as well as the kind of research that might be conducted, how long the information/biospecimen would be kept, and a disclosure that the subject will be made aware of neither the conduct of future research nor the results of that research. Research may be exempt with broad consent if an IRB determines, based on a “limited” review, that the following are present:

- Broad consent was properly obtained.
- Broad consent was properly documented (unless waived).
- The proposed activities are within the scope of the broad consent.
- Research results will not be communicated to subjects.

Waiver of informed consent

In order to waive or alter informed consent requirements, the IRB must determine that the research poses minimal risk to subjects, the waiver/alteration is necessary to “practicably” conduct the research, “the rights and welfare of the subjects” will be maintained, and subjects will be provided appropriate information later. In addition to this general rule, an IRB may also waive consent when an investigator wants to preliminarily gather data for the purpose of “screening, recruiting, or determining the eligibility of prospective subjects,” as long as such data are gathered through “oral or written communication” or from pre-existing records or biospecimens.

Posting of the informed consent form

For clinical trials conducted or supported by federal departments or agencies, a copy of the informed consent form must be posted to a yet-to-be-determined website within 60 days of the last study visit.

A Step Forward

The finalization of updates to modernize the Common Rule is a step toward simplifying the regulatory compliance requirements for those engaged in federal human subjects research, regardless of the federal entity involved. Despite this step toward harmonization, over the remainder of the year, stakeholders will need to devote resources toward reviewing their informed consent procedures, including training and updating internal control documents and, to the extent stakeholders participate in both federally supported and non-federally supported clinical research, ensuring that internal procedures incorporate the applicable requirements. We expect that there will be increased scrutiny applied to informed consent forms once they become publicly available through the new governmental website, not only by patients and their families, but also by researchers and developers as well as plaintiffs’ attorneys.

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