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ALERT

Health Care ▪ Life Sciences

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HHS Finalizes Major Changes to the Common Rule

On January 18, 2017, the U.S. Department of Health and Human Services (HHS), together with fifteen other federal Departments and Agencies, issued a final rule intended to revise and modernize the federal Policy for the Protection of Human Subjects (the Common Rule), the set of federal regulations governing clinical research involving human subjects. The final rule comes over 16 months after the Notice of Proposed Rulemaking (NPRM), which Ropes & Gray summarized here. Many of the provisions of the final rule will take effect in January 2018.

The final rule has implications for a wide range of stakeholders across the life sciences and health care industries, including drug and device manufacturers, hospitals, academic medical centers, universities and medical schools, institutional review boards (IRBs), contract research organizations, laboratories, and tissue banks.

Key differences between the NPRM and final rule:

- Most importantly, the final rule does not adopt the NPRM's proposal that research involving "human subjects" would include non-identifiable biospecimens. The NPRM would have required that researchers obtain consent from individuals before conducting clinical research on their non-identified biospecimens. In light of public comment vigorously opposed to that proposal, the final rule has rejected it, and reverts to the current status where biospecimens involved in research must be identifiable to be subject to the Common Rule.
- The final rule does not expand the Common Rule to cover clinical trials that are not federally funded.
- The final rule omits the NPRM proposal for more stringent criteria for obtaining a waiver of consent for research involving identifiable biospecimens.

Major provisions of the final rule:

- Will require that informed consent begin with a "concise and focused presentation of the key information" likely to help a prospective subject understand the reasons for and against participation. The information must be organized and presented in a manner that facilitates comprehension.
- Will permit researchers to obtain broad consent in lieu of specific consent with respect to the storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. Unlike the NPRM, the final rule does not provide for the federal government to develop a broad consent template.
- Will require that multi-site research use a single IRB for the portion of the research conducted in the U.S., except if prohibited by law or determined inappropriate by any federal Department or Agency supporting or conducting the research.
- Will create a new exempt category for secondary research involving identifiable private information if the research is already subject to the Health Insurance Portability and Accountability Act (HIPAA) rules.
- Will remove the continuing review requirement when the remaining research involves only data analysis or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

- Will require the public posting of consent forms for federally funded clinical trials, subject to certain redactions.

The final rule is on public display here, and HHS released a summary of the final rule, including changes made from the NPRM, available here. Ropes & Gray will publish a more detailed Alert on the final rule in the coming days.

If you have any questions, please contact any member of Ropes & Gray's health care or life sciences practices or your usual Ropes & Gray advisor.