ROPES & GRAY

ALERT

Health Care ▪ Life Sciences

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HHS Grants 30-Day Extension on Comment Period for Common Rule Revisions

Today, the Department of Health and Human Services ("HHS") published a Federal Register notice that extends the comment period for the Federal Policy for the Protection of Human Subjects ("Common Rule") notice of proposed rulemaking ("NPRM") by 30 days to **January 6, 2016**. As we noted on September 8, 2015, the NPRM would extensively revise the Common Rule (Title 45 of the Code of Federal Regulations, Part 46), and would mark the first systematic attempt to overhaul the set of regulations that govern research conducted, funded or otherwise subject to regulation by the federal government since its promulgation in 1991. The NPRM 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.

Of considerable importance to the life sciences and health care industries, the NPRM contains substantive proposals that would (i) significantly alter the regulatory framework for biospecimen research to require informed consent, even for de-identified biospecimen research, and limit the applicability of the waiver of consent mechanism; (ii) impose IRB and data security protection requirements on private entities that receive biospecimens collected during federally funded research; (iii) mandate single IRB review and approval of cooperative research; (iv) require posting of consent forms; (v) grandfather existing biospecimen collections when the research use of the biospecimens occurs after removal of any individually identifiable information associated with the biospecimens; and (vi) require that institutions, researchers, and life sciences companies implement detailed infrastructures to track broad consent and biospecimens.

To assist life sciences companies in understanding the complexities and implications of the NPRM, please refer to our in-depth Bloomberg BNA article.

The NPRM seeks active public engagement on the proposed codified text, on the numerous questions identified for public comment, and on the alternative schemes discussed in the preamble. As the NPRM accurately acknowledges, public trust in the research enterprise is imperative to the success and effectiveness of any changes to the Common Rule. The proposed rule will now be open for public comment until **January 6, 2016**. If you have any questions about the proposed revisions or how the NPRM may affect your organization, please contact any member of Ropes & Gray's health care or life sciences practices or your usual Ropes & Gray advisor.