Sweeping Changes under Consideration for "Common Rule" Human Subjects Protection Requirements

On July 22, 2011, the U.S. Department of Health and Human Services ("HHS") announced an Advance Notice of Proposed Rulemaking ("ANPRM") describing comprehensive potential revisions to the Common Rule. The Common Rule, which represents a common set of requirements for human subjects protection in research funded by fifteen federal agencies, was adopted in 1991. The ANPRM reflects HHS's intent to revise the regulatory requirements to address the evolution in the conduct of research over the last two decades. According to HHS, the volume of research conducted, the sites where research occurs, and the types of research conducted have all expanded. The technology used in research, including genomics, has also affected the conduct of research. The revisions under consideration are intended to enhance human subjects protection while simultaneously making the oversight of research less burdensome and inefficient.

To access Ropes & Gray's annotation of the HHS chart comparing existing and proposed rules, please click here. The key proposed revisions identified by HHS are:

- revising the existing risk-based framework so that the level of review is more accurately calibrated to the level of risk (*e.g.*, by expanding and defining better the activities subject to expedited Institutional Review Board ("IRB") review or excused from IRB review);
- using a single IRB review for all U.S. sites of multi-site studies;
- updating the forms and processes used for informed consent;
- establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data (which would include studies using biospecimens);
- implementing a systematic approach to the collection and analysis of data on "unanticipated problems" and "adverse events" across all trials to harmonize the current diverse reporting requirements and make the collection of data more efficient;
- extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies (whether or not the research is federally-funded); and
- providing uniform guidance on federal regulations.

In announcing the proposed revisions, HHS recognizes that other laws and regulations, such as the Food and Drug Administration ("FDA") regulations and the HIPAA Privacy Rule, will be affected and need to be harmonized with any revisions implemented.

The ANPRM, and additional guidance prepared by HHS on the ANPRM, is available here. (The ANPRM was also published in the Federal Register in July 26, 2011.) The HHS guidance includes a chart that compares the existing rules with the changes being considered.

Comments may be submitted on the ANPRM until 5:00 p.m. (EDT) on September 26, 2011 at www.regulations.gov under identification number: HHS-OPHS-2011-0005.

If you have questions about the ANPRM, please contact the Ropes & Gray attorney who normally advises you.

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