The Revised Common Rule—Facing an Uncertain Future?

Contracts Associates, Inc.

Jan. 17, 2018: The U.S. Department of Health and Human Services (HHS) has proposed a one-year delay in implementation of the revisions to the Common Rule. The updated rule was set to take effect on **January 19, 2018** with compliance expected on the same date. But, as of this writing, the effective date and the applicability of the revised Common Rule is uncertain.

During the waning days of the Obama administration, the final text of the updated Common Rule was released by HHS. Upon entering office, the Trump administration immediately froze all new or pending regulations left over from the previous administration to allow them to be reviewed by the new President's appointees. Implementation of the Common Rule changes was accordingly placed on hold.

What are the Revisions to the Common Rule?
The Common Rule, or the Federal Policy for the Protection of Human Subjects, is a set of regulations governing federally-funded research involving human participants, their data and biospecimens. First promulgated in 1991 and not updated since 2005, HHS proposed updating the Common Rule to reflect the rapidly-changing research landscape, especially in terms of human subject data and advancing digital technologies.

The revision process began in 2011 with the goal of enhancing protections of participants (relative to informed consent and data) and reducing administrative burdens. The Common Rule underwent significant revision with informed consent provisions requiring "a concise and focused presentation of the key information" in contracts. The updated rule also requires informed consent provisions to explain, among other things, the purposes of the research, risks and benefits of participation, and any appropriate alternatives so that a "reasonable person" can more easily decide whether or not to participate in the research.

In addition, the new rule requires that a version of the consent form that was used for enrollment purposes for each clinical trial be posted to a federal website. It also allows

for gaining broad consent for secondary research use of identifiable data and biospecimens of participants.

So What Happens Next?
The Office of Management and Budget (OMB) is currently reviewing the proposal by HHS to delay implementation and compliance by one year. Along with the one-year delay, HHS is considering allowing three burden-reducing provisions to be implemented during the delay to ease administration. Precisely which three provisions remains unclear as they have not been specifically enumerated and the proposal currently exists as a title with no accompanying text.

It is unclear whether both the effective and compliance date would be pushed back, or only the compliance date, or whether there will be no changes at all and the new rule will be fully implemented on **January 19, 2018**. The possibility of delay in compliance might be seen as good news to some institutions who are unprepared to comply with the new rule and need time to make necessary changes. But as of now, the future of the revised Common Rule is unknown.

Contracts Associates will continue to monitor the status of the revised Common Rule very carefully and will update this blog with any important new insights. If you have any questions about the changes, we encourage you to contact our office at 781-598-8000 or email our CEO, Colleen Sproul, at cms@contractsassociates.com so that we can provide you with the most current information regarding changes and compliance.