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Human Subject Protection

Early Adoption Not an Option For Research Rule Changes

Changes to human research subject protection regulations known as the Common Rule shouldn't be followed before they officially take effect next January, an HHS attorney said.

"You cannot start applying it right now. The current rule applies until the revised rule becomes effective," Laura M. Odwazny told a room full of health lawyers March 9 in Baltimore. Odwazny is the attorney who advises the Health and Human Services Office for Human Research Protections, which administers the Common Rule (45 C.F.R. 46).

Odwazny and Verrill Dana LLP research attorney Kate Gallin Heffernan delivered an update of the new Common Rule released in January during the American Health Lawyers Association's annual conference on legal issues affecting academic medical centers and teaching hospitals.

Shift From Single-Site to Global. The modernization of the Common Rule accounts for the shift away from a single-lab, single-site research model and toward a global research enterprise that incorporates rapidly advancing technologies in mobile health and genomics. The new rule ultimately dropped a controversial proposal to reclassify all biospecimens as human subjects—whether or not they can be identified—but kept a requirement that studies that take place in multiple locations use the same institutional review board (16 MRLR 51, 2/1/17).

The final rule culminated an effort from the early stages of then-President Barack Obama's administration to modernize regulations that hadn't been touched since 1991. Once effective, these changes will affect nearly 20 federal agencies, along with the institutions and scientists who receive their grant dollars.

'Truly a Midnight Rule.' "The revised Common Rule was published Jan. 19, 2017. Is that date significant?" Odwazny asked to laughter as it was also Obama's last day in office. "This was truly a midnight rule."

The effective date for the rule is Jan. 19, 2018, except for the single IRB provision. The HHS pushed back the date for that provision to Jan. 20, 2020, because of the complexity involved.

"What's important to remember," Odwazny said, "is this rule is not yet effective."

"You would not believe the number of questions I am getting about voluntary early compliance," she said.

Heffernan, who is a Bloomberg BNA health-care advisory board member, noted the proposed rule included language about voluntary compliance, but that option wasn't in the final version.

Grandfathering Option. When asked how institutions can prepare for the 2018 effective dates, Heffernan said studies approved by an IRB before Jan. 19, 2018, have the option of compliance with the existing rule throughout the study. But that option has to be documented and approved by the IRB.

"So studies from now until Jan. 19, get 'em in if you want to keep the existing rule because you have the option to do so," Heffernan said. "Or you can elect to morph and migrate into the new rule."

Both Heffernan and Odwazny said the changes are coming while there is regulatory uncertainty. President Donald Trump Feb. 24 signed a regulatory reform executive order that directed all federal agencies to form a task force to review all regulations. Odwazny also said Congress has the option of introducing a disapproval resolution and invalidating the new Common Rule. Congress has 60 legislative days, or days Congress is actually in session, rather than calendar days, from the Federal Register publication to disapprove of any given rule.

"That has not yet happened. I have no personal knowledge that anything like that is going to happen. But it could happen," Odwazny said.

At the same time, Heffernan said, institutions will have to start thinking about how to implement the revised Common Rule.

"They have to start getting their ducks in a row," she said. "They have to think about educating their communities and unfortunately that does have to start before we know whether or not this is going to survive so I think that's where we're at."

No More ‘Checking the Box.’ The Common Rule applies to federally funded research from HHS agencies like the National Institutes of Health, along with the Departments of Justice, Education, Energy and any other agencies, that have agreed to follow the regulation.

Institutions currently have the option of what’s commonly known as “checking the box” in the Federalwide Assurance they submit to the OHRP to show they will comply with the Common Rule. Checking the box means that all human subjects research will be subject to the Common Rule regardless of the funding source.

“Even though this flexibility in the Federalwide Assurance allowing the extension of the regulations to non-federally funded research is not a regulatory provision and doesn’t have anything to do specifically with the regulatory requirements in the revised final rule, the Office for Human Research Protections signaled the intention to have this checkbox go away,” she said.

“Thus, institutions will no longer have the flexibility for non-federally funded research to be covered under the jurisdiction of OHRP,” she said.

Because checking the box is an administrative action and not a regulatory action, Odwazny said, the time frame doesn’t have to be tied to that of the new rule.

“OHRP can pursue this in its own time and OHRP has already gotten some comments that it might be advantageous to the community to have this check still stay in place for awhile,” she said.

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More information on the AHILA conference is at <http://src.bna.com/mTm>.

The new Common Rule is at <http://src.bna.com/mTn>.