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Major Effects of Revised Common Rule on Regulation of Clinical Research in New York

On January 19, 2017, the U.S. Department of Health and Human Services (HHS), together with 15 other federal Departments and Agencies, issued a final rule¹ to revise and modernize the federal Policy for the Protection of Human Subjects (the Common Rule), the set of federal regulations governing the conduct of clinical research involving human subjects. We have described many of the key changes to federal regulations that are set to take effect under the Final Rule, starting in January 2018, in a previous [article](#) and [Alert](#). One important implication of the final rule for research conducted in the state of New York is the announcement that HHS will be eliminating the option for a research institution with a Federalwide Assurance (FWA) to commit voluntarily to comply with the Common Rule for its non-federally funded research (also known as “check the box”).²

An FWA is a written assurance of compliance with the Common Rule, and all institutions engaged in research funded by a Common Rule agency must submit an FWA to HHS’ Office for Human Research Protections (OHRP). Historically, research institutions filing an FWA have had the option to commit voluntarily to comply with the Common Rule for all human subjects research conducted at the institution, regardless of funding source. The preamble to the final rule states that this “voluntary extension will no longer be part of the assurance process and such research will not be subject to OHRP oversight.”³ The preamble explains that the goal of this change is to eliminate an unnecessary administrative burden on institutions that does not benefit human subject protections.

Notably, the final rule does not address the significant implication that removal of federal oversight for non-federally funded research will have on much human subjects research conducted in New York. Specifically, certain clinical research in that state may become subject to more rigorous New York State research requirements if that research is not regulated by OHRP under the Common Rule, and not regulated by the research requirements imposed by the Food and Drug Administration (FDA). (Non-federally funded research conducted in the state of Virginia will also become subject to state law requirements.)⁴

Regulation of Human Subjects Research in New York

Article 24-A of the New York Public Health Law (Article 24-A) regulates “human research,” defined as “any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject.”⁵ When human research conducted in New York is subject to federal research regulations, however, Article 24-A does not apply. According to Article 24-A, it “shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and

¹ [82 Fed. Reg. 7149](#).

² *See id.* at 7156, 7181.

³ *Id.* at 7181.

⁴ Virginia state law exempts human research that is “subject to policies and regulations for the protection of human subjects promulgated by any agency of the federal government.” Va. Code Ann. § 32.1-162.20.

⁵ N.Y. Pub. Health Law § 2441. “Human research” does not include the “conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or to include epidemiological investigations.”

regulations promulgated by any agency of the federal government for the protection of human subjects.”⁶ If an institution has “checked the box” on its FWA to subject all of its research to the Common Rule, then all of its human research is “subject to” regulations promulgated by a federal agency, and therefore not subject to Article 24-A. According to the commentary issued with the final rule, an institution will no longer be permitted to “check the box.” As a result of this change, a New York institution’s non-federally funded human research at that point will become subject to Article 24-A. The only other possibility for non-federally funded research in New York to avoid Article 24-A requirements will be if that research is subject to other federal research regulations, such as those of the FDA, although this has not been tested in a judicial forum and has not, to our knowledge, been the subject of any guidance from New York State authorities.

The expansion in the application of Article 24-A to human subjects research conducted in New York State is important because its requirements are in some respects much more rigorous than those of the Common Rule, most notably, (i) Article 24-A does not allow for the waiver of informed consent,⁷ and (ii) requires the Commissioner of the New York State Department of Health to approve each individual interventional research protocol involving minors, incompetent persons, mentally disabled persons, and prisoners, even when the research has been approved by the state equivalent of an institutional review board.⁸

Because FWAs are valid for a period of five years, it is unclear at this time how OHRP will treat institutions that checked the box on an FWA that does not expire until after the January 19, 2018 effective date of the final rule. Presumably, OHRP will issue guidance and provide some transition period, though this has not yet been clarified.

Ropes & Gray will continue to monitor any developments in this area from OHRP and at the state level. If you have any questions, please contact any member of Ropes & Gray’s [health care](#) practice or your usual Ropes & Gray advisor.

⁶ *Id.* at § 2445.

⁷ *Id.* at § 2442.

⁸ *Id.* at § 2444.