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FDA 2018 Year in Review: Clinical Investigations

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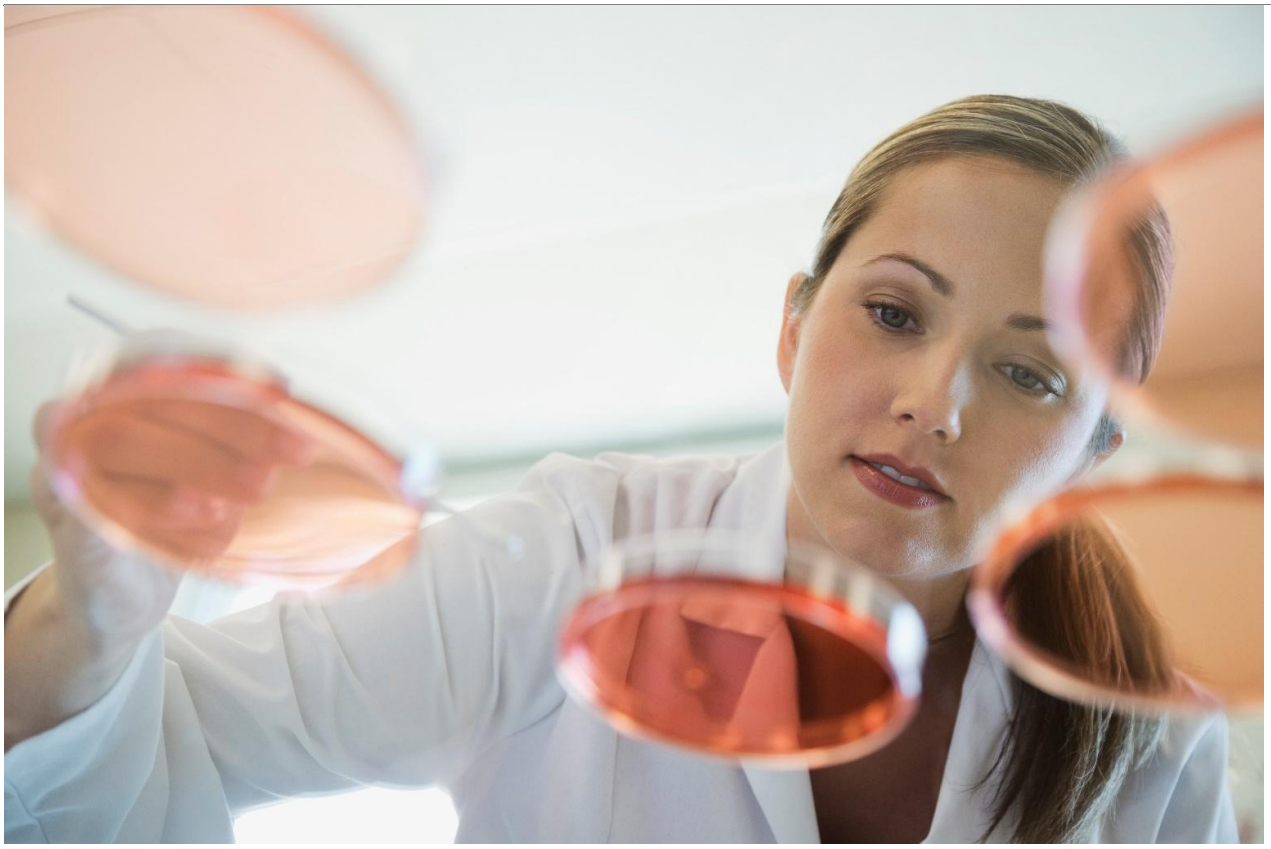
Developments in 2018

On October 12, FDA published guidance offering interim direction for researchers, sponsors and Institutional Review Boards (IRBs) engaging in both FDA-regulated clinical trials and federally sponsored human subjects research regulated by the overarching rule known as the Common Rule. The Cures Act directed the Secretary of HHS to work to harmonize FDA's clinical research regulations with the Common Rule . This effort is of increased importance as the numerous federal agencies and departments that have adopted the Common Rule adopted sweeping revisions to the law, which are fully effective on January 21, 2019.

While the guidance document, Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations, only provides limited guidance while more extensive FDA rulemaking is forthcoming, it provides FDA's current position and thinking on two important topics:



- **Informed Consent.** The updated Common Rule includes several new requirements for informed consent, including changes to the content, organization and presentation of information to human subjects. FDA clarified that such additional elements could be built into the consent process for FDA-regulated clinical trials and that two consent forms would not be required, as the two rules are not inconsistent.

- **IRB Review.** The updated Common Rule presumes that studies that meet a list of eligible categories will not involve more than minimal risk, permitting them to qualify for expedited review by an IRB, while FDA's rules require an IRB to affirmatively make a risk determination. Similarly, the updated Common Rule eliminated the requirement for continuing IRB review for certain studies, whereas FDA's rules require continuing review. FDA acknowledged these changes but confirmed that FDA-regulated clinical trials must still follow the FDA's rules, which would not permit studies subject to both laws to benefit from the new pathways for decreased IRB oversight built into the new Common Rule.

At a high level, FDA also confirmed that in the event of a conflict between its regulations and the Common Rule, researchers are to follow the regulations that offer the greatest protection to human subjects. Given FDA's signal that the agency is "actively working" to harmonize its regulations with the Common Rule, additional formal rulemaking could be on the horizon in 2019, particularly on the topics addressed in the guidance.

Read more on FDA 2018 Year in Review.

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