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In Case You Forgot: New Common Rule Informed Consent Requirements

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Last month, the Food and Drug Administration issued a short guidance document to help researchers and institutions understand how the new Common Rule intersects with FDA regulations. Spoiler: as promised, FDA plans to issue its own regulations, but it's not clear when or what they'll say. The new consent provisions, FDA said, are "not incompatible" with FDA's rules, but the agency isn't as keen on lack of continuing review or new expedited review categories (*RRC 10/18/18*).

Such guidance is necessary, FDA acknowledged, because it never adopted the revised Common Rule, which goes into effect Jan. 21 for all provisions other than the use of a single institutional review board (IRB). While the FDA document itself is not terribly detailed, it does provide a high-level overview of the major provisions in the revised rule.

In particular, the guidance contains the following summary of changes to informed consent:

"**A. General Requirements for Informed Consent**